

COURT APPROVED PROTOCOL
TRACEBACK PROCEDURE CRITERIA

REVISED DECEMBER, 2017

This protocol sets out the criteria for Traceback Procedures referred to in sections 3.03, 3.04, 3.05(6) of the Transfused HCV Plan and 3.03, 3.04Tran and 3.05(6) of the HCV Late Claims Benefit Plan

DEFINED TERMS AND PROVISIONS APPLICABLE TO THIS PROTOCOL

1. In addition to the defined terms contained in the Transfused HCV Plan and the HCV Late Claims Benefit Plan (which appear herein as capitalized words), the following defined terms are used in this protocol:
 - (a) **“Traceback Procedure”** means a targeted search for and investigation of the donor and/or the units received by a claimant in Canada and, for the purpose of this protocol, includes any one or more of the following stages of search: a Records Search, a Class Period Search and/or a Pre-Class Period Search;
 - (b) **“Records Search”** means that stage of Traceback Procedure where a search is conducted to match the units received by a claimant at any time against the records of Canadian Blood Services (“CBS”) and Hema-Quebec to determine if the HCV antibody status of the donor of some or all of the units received is known;
 - (c) **“Class Period Search”** means that stage of Traceback Procedure where attempts are made to locate the donors of the units received by a claimant during the Class Period and, where necessary, to have the donor tested to determine his or her HCV antibody status;
 - (d) **“Pre-Class Period Search”** means that stage of Traceback Procedure where attempts are made to locate the donors of the units received by a claimant before the Class Period and, where necessary, to have the donor tested to determine his or her HCV antibody status;
 - (e) **“Lookback notification”** means notification that the claimant received units from a donor who, on subsequent donation or testing, is confirmed to be HCV antibody positive.
2. For the purposes of this protocol, where the words transfusion, donor and/or unit are used in reference to a Claim they refer to the claimant’s receipt of Blood as defined under the Transfused HCV Plan and where they are used in reference to a Late Claim they refer to

the claimant's receipt of Blood (Transfused) as defined under the HCV Late Claims Benefit Plan and claimant refers to a person claimed to be a Primarily-Infected Person.

COMPLETION AND/OR DISCONTINUANCE OF THE TRACEBACK PROCEDURE

3. For the purposes of this protocol:

- (a) a Traceback Procedure shall be deemed complete and all further Traceback Procedure efforts under this protocol relating to a Claim or Late Claim discontinued where:
 - (i) the claimant received units only during the Class Period or only during and after the Class Period and:
 - A. one of the donors or units he or she received during the Class Period is determined to be HCV antibody positive; or
 - B. all of the donors or units he or she received during the Class Period are determined not to be HCV antibody positive; or
 - (ii) the claimant received units before and during the Class Period or before, during and after the Class Period and:
 - A. one of the donors or units he or she received before the Class Period is determined to be HCV antibody positive;
 - B. all of the donors or units he or she received during the Class Period are determined not to be HCV antibody positive; or
 - C. all of the donors or units he or she received before the Class Period are determined not to be HCV antibody positive and one of the donors or units he or she received during the Class Period is determined to be HCV antibody positive;
- (b) all further Class Period Search and/or Pre-Class Period Search efforts under this protocol relating to a Claim or a Late Claim shall be discontinued once the Administrator has made its decision to accept or reject that Claim or Late Claim. Subsequent periodic Record Search updates may be required in respect of some Claims or Late Claims as provided in paragraph 13 of this protocol.

THE ADMINISTRATOR'S DECISION TO ACCEPT OR REJECT A CLAIM OR LATE CLAIM

4. In making its decision whether the Claim or Late Claim in respect of a claimant, the Administrator shall:

- (a) obtain and assess the results of the stage or stages of Traceback Procedure required by such of paragraphs 6 to 11 of this protocol as are applicable to the Claim or Late Claim in question;
 - (b) carry out additional investigation where one or more of the type of indicia enumerated at paragraph 11 of this protocol are present; and
 - (c) where required by the provisions of paragraphs 10(e), 10(f)(ii) or 11(d)(iv) of this protocol and/or where the Administrator undertook additional investigation as required by paragraph 4(b) of this protocol, consider whether all of the information available to the Administrator when weighed together establishes to the satisfaction of the Administrator on the balance of probabilities, that the claimant was infected with HCV for the first time prior to the Class Period (the “Balance of Probabilities Analysis”).
5. Subject to the other requirements in paragraph 4 of this protocol, the Administrator shall make its decision to accept or reject the Claim or Late Claim, notwithstanding that a Class Period Search and/or a Pre-Class Period Search may not have been completed:
- (a) when the Administrator is of the view that in all of the circumstances a Class Period Search and/or a Pre-Class Period Search is unlikely to yield any further information that will assist in assessing the Claim or Late Claim; and
 - (b) notwithstanding subparagraph (a) above, no later than 6 months after the date on which the claimant has met the requirements of sections 3.01(1)(a) and (b) of the Transfused HCV Plan or sections 3.01Tran(1)(a) and (b) of the HCV Late Claims Benefits Plan and provided the Authorization to Initiate Traceback Procedure and/or to Release Information Form and the Transfusion History Form, whichever is later, unless:
 - (i) the transfusion information concerning the claimant provided on or with the Transfusion History Form was incomplete or inaccurate, in which case the 6 months will begin to run from the time the Administrator determines the transfusion information is complete; or
 - (ii) the time is extended with the consent of the claimant or by a Court on a teleconference motion made by Fund Counsel on notice to the claimant.;

The Administrator shall take reasonable steps to assist the claimant to identify unit numbers for transfusions received by the claimant where that information was not provided in the Forms, records and/or in the available Traceback Procedure information. In its discretion, the Administrator may relieve against the requirement to identify all unit numbers for transfusions received where the claimant received Blood only during the Class Period or only during and after the Class Period and a negative is indicated on the Pre-Approval Tables annexed hereto when applied to his or her transfusion history.

OBTAIN AND ASSESS AVAILABLE TRACEBACK PROCEDURE INFORMATION

6. The Administrator shall obtain and assess the results of any Traceback Procedure in respect of a person claimant initiated without the involvement of the Administrator. If the Traceback Procedure is complete or can be deemed complete as provided in paragraph 3 herein, the Administrator shall accept or reject the Claim or Late Claim:
 - (a) where transfusions were received only during the Class Period or only during and after the Class Period, by applying the appropriate subparagraph of paragraph 8 below; or
 - (b) where transfusions were received before and during the Class Period or before, during and after the Class Period, by applying the appropriate subparagraph in paragraphs 9 to 11 below.

INITIATE A RECORDS SEARCH

7. In each case where there is no conclusive Lookback notification or the available Traceback Procedure information, if any, is insufficient to allow the Administrator to make its decision to accept or reject a Claim, the Administrator shall initiate a Records Search of those units received by the claimant in respect of which the HCV antibody status is unknown and:
 - (a) where transfusions were received only during the Class Period or only during and after the Class Period, proceed as directed in paragraph 8 below; or
 - (b) where Blood transfusions were received before and during the Class Period or before, during and after the Class Period, proceed as directed in paragraphs 9 to 11 below.

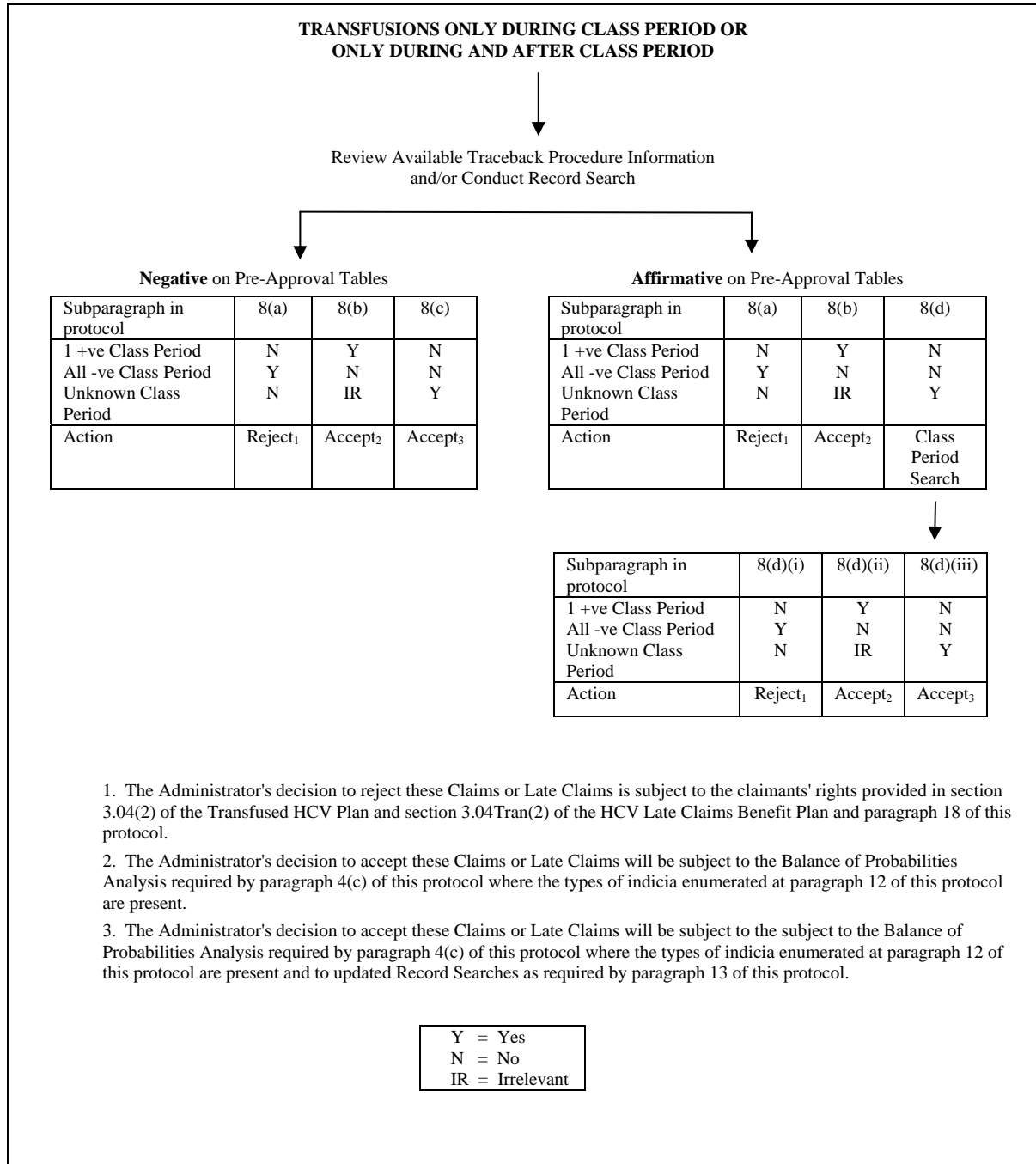
WHERE TRANSFUSIONS WERE RECEIVED IN CANADA ONLY DURING THE CLASS PERIOD OR ONLY DURING AND AFTER THE CLASS PERIOD

8. After reviewing the available Traceback Procedure information, if any, and the results of the Records Search, if such was required, the Administrator shall:
 - (a) where all of the donors or units received by the claimant during the Class Period are determined not to be HCV antibody positive, reject the Claim or Late Claim as provided in section 3.04(1) of the Transfused HCV Plan or section 3.04Tran(1) of the HCV Late Claims Benefit Plan, as applicable, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in section 3.04(2) of the Transfused HCV Plan or section 3.04Tran(2) of the HCV Late Claims Benefit Plan, as applicable, and paragraph 18 of this protocol;
 - (b) where one or more of the donors or units received by the claimant during the Class Period is determined to be HCV antibody positive, accept the Claim or Late Claim, subject to the effect, if any, of the Balance of Probabilities Analysis the

Administrator may be required to perform as provided in paragraph 4(c) of this protocol;

- (c) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraph (a) or (b) of this paragraph, the HCV antibody status of one or more of the donors or units received by the claimant during the Class Period remains unknown and a negative is indicated on the applicable Pre-Approval Tables annexed hereto when applied to his or her transfusion history, accept the Claim or Late Claim in reliance on the presumption provided for in the definition of Primarily-Infected Person in the applicable Plan, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 3(c) of this protocol; or
- (d) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraph (a) or (b) of this paragraph, the HCV antibody status of one or more of the donors or units received by the claimant during the Class Period remains unknown and an affirmative is indicated on the applicable Pre-Approval Tables annexed hereto when applied to his or her transfusion history, initiate a Class Period Search and after reviewing the results proceed as follows:
 - (i) where all of the donors or units received by the claimant during the Class Period are determined not to be HCV antibody positive by the Class Period Search, reject the Claim as provided in section 3.04(1) of the Transfused HCV Plan or section 3.04Tran(1) of the HCV Late Claims Benefit Plan as applicable, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in section 3.04(2) of the Transfused HCV Plan or section 3.04Tran(2) of the HCV Late Claims Benefit Plan, as applicable and paragraph 18 of this protocol;
 - (ii) where one or more of the donors or units received by the person claimed to be a Primarily-Infected Person during the Class Period is determined to be HCV antibody positive by the Class Period Search, accept the Claim or Late Claim, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol; or
 - (iii) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraph (d)(i) or (d)(ii) of this paragraph and the HCV antibody status of one or more of the donors or units received by the claimant during the Class Period remains unknown following the Class Period Search, accept the Claim or Late Claim in reliance on the presumption provided for in the definition of Primarily-Infected Person in the applicable Plan, subject to the effect, if any, of the results of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol.

The directions contained in this paragraph are also depicted in the following flowchart:



WHERE TRANSFUSIONS WERE RECEIVED IN CANADA BEFORE AND DURING THE CLASS PERIOD OR BEFORE, DURING AND AFTER THE CLASS PERIOD

9. After reviewing the available Traceback Procedure information, if any, and the results of the Records Search, if such was required, the Administrator shall:

- (a) where one or more of the donors or units received by the claimant before the Class Period is determined to be HCV antibody positive, reject the Claim or Late Claim as provided in section 3.04(1) of the Transfused HCV Plan or section 3.04Tran(1) of the HCV Late Claims Benefit Plan, as applicable, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in section 3.04(2) of the Transfused HCV Plan or section 3.04Tran(2) of the HCV Late Claims Benefit Plan, as applicable, and paragraph 18 of this protocol;
 - (b) where all of the donors or units received by the claimant during the Class Period are determined not to be HCV antibody positive, reject the Claim or Late Claim as provided in section 3.04(1) of the Transfused HCV Plan or section 3.04Tran(1) of the HCV Late Claims Benefit Plan, as applicable, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in section 3.04(2) of the Transfused HCV Plan or section 3.04Tran(2) of the HCV Late Claims Benefit Plan, as applicable, and paragraph 18 of this protocol;
 - (c) where all of the donors or units received by the claimant before the Class Period are determined not to be HCV antibody positive and one or more of the donors or units he or she received during the Class Period is determined to be HCV antibody positive, accept the Claim or Late Claim, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol;
 - (d) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraphs (a) to (c) of this paragraph, all of the donors or units received by the claimant before the Class Period are determined not to be HCV antibody positive, the HCV antibody status of some of the donors or units he or she received during the Class Period remains unknown and a negative is indicated on the applicable Pre-Approval Tables annexed hereto when applied to his or her transfusion history, accept the Claim or Late Claim in reliance on the presumption provided for in the definition of Primarily-Infected Person in the applicable Plan, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol; or
 - (e) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraphs (a) to (d) of this paragraph and the HCV antibody status of one or more of the donors or units received by the claimant before or during the Class Period remains unknown, after considering how to most expeditiously investigate the transfusions, initiate a Class Period Search and/or a Pre-Class Period Search on the remaining units he or she received.
10. Where a Pre-Class Period Search was initiated pursuant to subparagraph 9(e) above, the Administrator shall:

- (a) where one or more of the donors or units received by the claimant before the Class Period is determined to be HCV antibody positive by the Pre-Class Period Search, reject the Claim or Late Claim as provided in section 3.04(1) of the Transfused HCV Plan or section 3.04Tran(1) of the HCV Late Claims Benefit Plan, as applicable, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in section 3.04(2) of the Transfused HCV Plan or section 3.04(2) of the HCV Late Claims Benefit Plan, as applicable, and paragraph 18 of this protocol;
- (b) where all of the donors or units received by the claimant before the Class Period are determined not to be HCV antibody positive by the Pre-Class Period Search and one or more of the donors or units received during the Class Period has already been determined to be HCV antibody positive, accept the Claim or Late Claim, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol;
- (c) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraph (a) or (b) of this paragraph, all of the donors or units received by the claimant before the Class Period are determined not to be HCV antibody positive by the Pre-Class Period Search and the HCV antibody status of some or all of the donors or units he or she received during the Class Period remains unknown and a negative is indicated on the applicable Pre-Approval Tables annexed hereto when applied to his or her transfusion history, accept the Claim or Late Claim in reliance on the presumption provided for in the definition of Primarily-Infected Person in the applicable Plan, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol;
- (d) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraphs (a) to (c) of this paragraph, all of the donors or units received by the claimant before the Class Period are determined not to be HCV antibody positive by the Pre-Class Period Search,

the HCV antibody status of some or all of the donors or units he or she received during the Class Period remains unknown and an affirmative is indicated on the applicable Pre-Approval Tables annexed hereto when applied to his or her transfusion history, initiate a Class Period Search of the remaining units received by the claimant during the Class Period and after reviewing the results proceed as follows:

- (i) where all of the donors or units received by the claimant during the Class Period are determined not to be HCV antibody positive by the Class Period Search, reject the Claim or Late Claim as provided in section 3.04(1) of the Transfused HCV Plan or section 3.04Tran(1) of the HCV Late Claims Benefit Plan, as applicable, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in section 3.04(2) of the Transfused HCV Plan or section 3.04Tran(2) of the

HCV Late Claims Benefit Plan, as applicable, and paragraph 18 of this protocol;

- (ii) where one or more of the donors or units received by the claimant during the Class Period is determined to be HCV antibody positive by the Class Period Search, accept the Claim or Late Claim, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol;
 - (iii) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraph (d)(i) or (d)(ii) of this paragraph and the HCV antibody status of one or more of the donors or units received by the claimant during the Class Period remains unknown following the Class Period Search, accept the Claim or Late Claim in reliance on the presumption provided for in the definition of Primarily-Infected Person in the applicable Plan, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol;
- (e) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraphs (a) to (d) of this paragraph, the HCV antibody status of some or all of the donors or units received by the claimant before the Class Period remains unknown following the Pre-Class Period Search and one or more of the donors or units he or she received during the Class Period has already been determined to be HCV antibody positive, accept the Claim or Late Claim in reliance on the presumption provided for in the definition of Primarily-Infected Person in the applicable Plan, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol; or
- (f) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraph (a) to (d) of this paragraph, the HCV antibody status of some of the donors or units received by the claimant before the Class Period remains unknown following the Pre-Class Period Search and the HCV antibody status of some or all of the donors or units he or she received during the Class Period remains unknown, initiate a Class Period Search of the remaining units received by the claimant during the Class Period and after reviewing the results proceed as follows:
- (i) where all of the donors or units received by the claimant during the Class Period are determined not to be HCV antibody positive by the Class Period Search, reject the Claim or Late Claim as provided in section 3.04(1) of the Transfused HCV Plan or section 3.04Tran(1) of the HCV Late Claims Benefit Plan, as applicable, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in section 3.04(2) of the Transfused HCV Plan or section 3.04Tran(2) of the

HCV Late Claims Benefit Plan, as applicable and paragraph 18 of this protocol; or

- (ii) where the Claim or Late Claim cannot be rejected as provided in subparagraph (f)(i) of this paragraph following the Class Period Search, accept the Claim or Late Claim in reliance on the presumption provided for in the definition of Primarily-Infected Person in the applicable Plan, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol.

11. Where a Class Period Search was initiated pursuant to subparagraph 9(e) above, the Administrator shall:

- (a) where all of the donors or units received by the claimant during the Class Period are determined not to be HCV antibody positive by the Class Period Search, reject the Claim or Late Claim as provided in section 3.04(1) of the Transfused HCV Plan or section 3.04Tran(1) of the HCV Late Claims Benefit Plan, as applicable, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in section 3.04(2) of the Transfused HCV Plan or section 3.04Tran(2) of the HCV Late Claims Benefit Plan, as applicable, and paragraph 18 of this protocol;
- (b) where one or more of the donors or units received by the claimant during the Class Period is determined to be HCV antibody positive by the Class Period Search and all of the donors or units he or she received before the Class Period have already been determined not to be HCV antibody positive, accept the Claim or Late Claim, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol;
- (c) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraph (a) or (b) of this paragraph, the HCV antibody status of one or more of the donors or units received by the claimant during the Class Period remains unknown following the Class Period Search and all of the donors or units he or she received before the Class Period have already been determined not to be HCV antibody positive, accept the Claim or Late Claim in reliance on the presumption provided for in the definition of Primarily-Infected Person in the applicable Plan, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol; or
- (d) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraphs (a) to (c) of this paragraph, none of the donors or units received by the claimant before the Class Period have been determined to be HCV antibody positive and the HCV antibody status of some of the donors or units he or she received before the Class Period remains unknown, initiate a Pre-Class Period

Search on the remaining units received by the claimant before the Class Period and after reviewing the results proceed as follows:

- (i) where one or more of the donors or units received by the claimant before the Class Period is determined to be HCV antibody positive following the Pre-Class Period Search, reject the Claim or Late Claim as provided in section 3.04(1) of the Transfused HCV Plan or section 3.04Tran(1) of the HCV Late Claims Benefit Plan, as applicable, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in section 3.04(2) of the Transfused HCV Plan or section 3.04Tran(2) of the HCV Late Claims Benefit Plan, as applicable and paragraph 18 of this protocol;
- (ii) where all of the donors or units received by the claimant before the Class Period are determined not to be HCV antibody positive following the Pre-Class Period Search and one or more of the donors or units he or she received during the Class Period has already been determined to be HCV antibody positive, accept the Claim or Late Claim, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol;
- (iii) where all of the donors or units received by the claimant before the Class Period are determined not to be HCV antibody positive following the Pre-Class Period Search, the HCV antibody status of one or more of the donors or units he or she received during the Class Period remains unknown and none of the donors or units received during the Class Period have been determined to be HCV antibody positive, accept the Claim or Late Claim in reliance on the presumption provided for in the definition of Primarily-Infected Person in the applicable Plan, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol; or
- (iv) where the Claim or Late Claim can neither be accepted nor rejected as provided in subparagraphs (d)(i) to (d)(iii) of this paragraph and the HCV antibody status of some or all of the units received by the person claimant before the Class Period remains unknown following the Pre-Class Period Search regardless of whether or not one or more of the donors or units he or she received during the Class Period has already been determined to be HCV antibody positive, accept the Claim or Late Claim in reliance on the presumption provided for in the definition of Primarily-Infected Person in the applicable Plan, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 4(c) of this protocol.

The directions contained in paragraphs 9, 10 and 11 are also depicted in the following flowchart:

TRANSFUSIONS BOTH BEFORE AND DURING CLASS PERIOD OR
BEFORE, DURING AND AFTER CLASS PERIOD



Review Available Traceback Procedure Information and/or
Conduct Records Search

Subparagraph in Protocol	9(a)	9(b)	9(c)	9(d)	9(e)
1 +ve Pre-Class	Y	IR	N	N	N N N
All -ve Pre-Class	N	IR	Y	Y	N Y N
Unknown Pre-Class	IR	IR	N	N	Y N Y
1 +ve Class	IR	N	Y	N	Y N N
All -ve Class	IR	Y	N	N	N N N
Unknown Class	IR	N	IR	Y	IR Y Y
Action	Reject ₁	Reject ₁	Accept ₂	Accept (if the negative is indicated on Pre-Approval Tables) ₃	Pre-Class and/or Class Period Search



Pre-Class Period Search

Subparagraph in Protocol	10(a)	10(b)	10(c)	10(d)	10(f)	10(e)
1 +ve Pre-Class	Y	N	N	N	N	N
All -ve Pre-Class	N	Y	Y	Y	N	N
Unknown Pre-Class	IR	N	N	N	Y	Y
1 +ve Class	IR	Y	N	N	N	Y
All -ve Class	IR	N	N	N	N	N
Unknown Class	IR	IR	Y	Y	Y	IR
Action	Reject ₁	Accept ₂	Accept (if the negative is indicated on Pre-Approval Tables) ₃	Class Period Search	Undertake Balance of Probabilities Analysis ₄	



Class Period Search

Subparagraph in Protocol	10(d)(i) 10(f)(i)	10(d)(ii)	10(d)(iii)	10(f)(ii)
1 +ve Pre-Class	IR	N	N	N N
All -ve Pre-Class	IR	Y	Y	N N
Unknown Pre-Class	IR	N	N	Y Y
1 +ve Class	N	Y	N	N Y
All -ve Class	Y	N	N	N N
Unknown Class	N	IR	Y	Y IR
Action	Reject ₁	Accept ₂	Accept ₃	Undertake Balance of Probabilities Analysis ₄



Class Period Search

Subparagraph in Protocol	11(a)	11(b)	11(c)	11(d)
1 +ve Pre-Class	IR	N	N	N N
All -ve Pre-Class	IR	Y	Y	N N
Unknown Pre-Class	IR	N	N	Y Y
1 +ve Class	N	Y	N	Y N
All -ve Class	Y	N	N	N N
Unknown Class	N	IR	Y	IR Y
Action	Reject ₁	Accept ₂	Accept ₃	Pre-Class Period Search



Pre-Class Period Search

Subparagraph in Protocol	11(d)(i)	11(d)(ii)	11(d)(iii)	11(d)(iv)
1 +ve Pre-Class	Y	N	N	N N
All -ve Pre-Class	N	Y	Y	N N
Unknown Pre-Class	IR	N	N	Y Y
1 +ve Class	IR	Y	N	Y N
All -ve Class	IR	N	N	N N
Unknown Class	IR	IR	Y	IR Y
Action	Reject ₁	Accept ₂	Accept ₃	Undertake Balance of Probabilities Analysis ₄

1. The Administrator's decision to reject these Claims or Late Claims is subject to the claimants' rights provided in section 3.04(2) of the Transfused HCV Plan, section 3.04Tran(2) of the HCV Late Claims Benefit Plan and paragraph 18 of this Protocol.
2. The Administrator's decision to accept these Claims or Late Claims will be subject to the Balance of Probabilities Analysis required by paragraph 4(c) of this Protocol where the types of indicia enumerated at paragraph 12 of this Protocol are present.
3. The Administrator's decision to accept these Claims or Late Claims will be subject to the subject to the Balance of Probabilities Analysis required by paragraph 4(c) of this Protocol where the types of indicia enumerated at paragraph 12 of this Protocol are present and to updated Record Searches as required by paragraph 13 of this Protocol.
4. The Administrator's decision to accept these Claims or Late Claims will be subject to the Balance of Probabilities Analysis required by paragraph 4 (c) of this Protocol and to updated Record Searches as required by paragraph 13 of this Protocol.

Y = Yes
N = No
IR = Irrelevant

INDICATIONS FOR ADDITIONAL INVESTIGATION

12. The Administrator shall review such records, Forms, documentation and/or information it receives pertaining to the person claimed to be a Primarily-Infected Person to determine if there is any indication for additional investigation, including:
- (a) any indication of non-prescription intravenous drug use by the claimant, notwithstanding that the claimant provided the required declaration;
 - (b) a failure to provide a declaration of knowledge, information and belief that the claimant was not infected with Hepatitis Non-A Non-B or the Hepatitis C virus prior to January 1, 1986;
 - (c) a prior application to another government HCV compensation program and/or a declaration of knowledge, information or belief that the claimant was infected with HCV by blood received before January 1, 1986;
 - (d) any indication of transfusion information that conflicts with the information provided on the Forms submitted;
 - (e) a relationship with the Treating Physician which appears to be of a transitory nature;
 - (f) any indication of the existence of Hepatitis B, a previous unspecified Hepatitis or liver irregularity by the person claimed to be a Primarily-Infected Person prior to his or her first transfusion during the Class Period;
 - (g) any indication of the existence of a major surgical procedure, disease, treatment or trauma that was likely to have required a transfusion but which was not detailed in the answers provided in the Forms submitted to the Administrator;
 - (h) any indication of one or more of the risk factor(s) outlined in the Treating Physician Form either from the Treating Physician or in the other documentation received;
 - (i) receipt of any transfusions outside Canada at any time prior to his or her diagnosis with HCV; and/or
 - (j) an inconclusive Traceback Procedure result;

and conduct such additional investigation as to it seems appropriate for the Claim or Late Claim in question, which may include obtaining additional documentation and/or medical examination as provided in section 3.03 of the Transfused HCV Plan or section 3.03 of the HCV Late Claims Benefit Plan, as applicable.

PERIODIC UPDATE OF THE RECORDS SEARCH IN SOME CASES

13. The Administrator shall, after having made its decision to accept or reject a Claim or Late Claim as provided in subparagraph 8(c), 8(d)(iii), 9(d), 10(c), 10(d)(iii), 10(e), 10(f)(ii), 11(c), 11(d)(iii) or 11(d)(iv), periodically update the Records Search of the relevant units received by the claimant for which the HCV antibody status remains unknown to determine if there is any additional information with which to re-assess its decision in respect of the Claim or Late Claim.
14. Where a Claim or Late Claim is accepted, it may later be rejected if information concerning the HCV antibody status of the donors or units received by the claimant or other means of infection becomes known which would have resulted in rejection of the Claim or Late Claim had that information been considered at the time the Administrator's decision was taken. The claimant shall thereafter become disentitled to future payments under the applicable Plan. Absent fraud on the part of the claimant, the claimant shall not be obligated to repay any monies received under the applicable Plan prior to becoming disentitled under the applicable Plan.
15. Where a Claim or Late Claim is rejected, it may later be accepted if information concerning the HCV antibody status of the donors or units received by the claimant becomes known which would have resulted in acceptance of the Claim or Late Claim had the information been considered at the time the original decision was taken. The claimant shall become entitled to the relevant payments under the applicable Plan.

REPORTING

16. The Administrator shall, where it has received sufficient Traceback Procedure information from CBS or Hema-Quebec to make its decision to accept or reject a Claim or Late Claim, request CBS or Hema-Quebec to provide a report of available Traceback Procedure information to the claimant.

CONFIDENTIALITY

17. The Administrator shall not use or disclose the information obtained pursuant to the Traceback Procedure other than for the purpose of performing its obligation pursuant to Ontario and British Columbia judgments dated October 22, 1999, the Quebec judgment dated November 19, 1999, the orders of the Courts approving the HCV Late Claims Benefit Plan and any other relevant court orders and for no other improper purpose. Any person to whom the Administrator discloses the information obtained pursuant to the Traceback Procedure in performing its obligations pursuant to the fulfilment of the said judgments and orders shall not use the Traceback Procedure information for any purpose other than the fulfilment of the said judgments and orders.

SECTION 3.04(1) – REJECTION OF CLAIM OR LATE CLAIM

18. The Administrator shall, after determining in accordance with the provisions of section 3.04(1) of the Transfused HCV Plan or section 3.04Tran(1) of the HCV Late Claims Benefit Plan, as applicable, and subparagraph 8(a), 8(d)(i), 9(a), 9(b), 10(a), 10(d)(i),

10(f)(i), 11(a) or 11(d)(i) above that a Claim or Late Claim must be rejected based upon the Traceback Procedure result, advise the claimant that, unless the claimant provides further evidence of first infection (“Further Evidence of First Infection”) which establishes to the satisfaction of the Administrator that the person claimed to be the Primarily-Infected Person was infected for the first time with HCV by a transfusion received in Canada during the Class Period notwithstanding the Traceback Procedure result in accordance with section 3.04(2) of the Transfused HCV Plan or section 3.04Tran(2) of the HCV Late Claims Benefit Plan, as applicable, his or her claim shall be rejected (a “Section 3.04/3.04Tran Letter”).

19. A Section 3.04/3.04Tran Letter shall advise the claimant that he or she may elect to provide Further Evidence of First Infection by returning the election form provided to the Administrator within thirty days from the date of receipt of the Section 3.04/3.04Tran Letter, failing which his or her Claim or Late Claim shall be rejected.
20. If the claimant elects to provide Further Evidence of First Infection and returns the prescribed election form in the prescribed time, he or she must provide, within the following six months, his or her Further Evidence of First Infection, unless that time is extended with the consent of the Administrator or by the Court on a teleconference motion arranged at the request of the claimant.
21. The Administrator shall, following receipt and consideration of the Further Evidence of First Infection received from a claimant, accept or reject his or her Claim or Late Claim based upon all of the information available to the Administrator and section 3.04 of the Transfused HCV Plan or section 3.04Tran of the HCV Late Claims Benefit Plan, as applicable.
22. If the claimant who elected to provide Further Evidence of First Infection does not provide the Further Evidence of First Infection within the six months following his or her election, or such further time as has been agreed or ordered, his or her Claim or Late Claim shall be rejected.

APPEAL RIGHTS

23. Where the Administrator rejects a Claim or Late Claim, it shall advise the claimant of his or her appeal rights under the applicable Plan.

RESULTS OF CERTAIN FROZEN SAMPLES

24. Notwithstanding the foregoing provisions of this protocol, no test result in respect of a frozen blood sample maintained by Canadian Blood Services shall be taken into consideration for the purpose of including or excluding any HCV Infected Person under the Transfused HCV Plan or the HCV Late Claims Benefit Plan.

PRE-APPROVAL TABLE 1 For use with male transfusion recipient							
Year of Birth							
		# of units transfused	1970+	1960-69	1945-59	1935-44	<1935
Year of Transfusion	1986	1-4	Y ₁	Y	Y	Y	N
		5-9	Y ₁	Y	Y	Y	N
		10-14	N	Y	Y	Y	N
		15-24	N	Y	Y	N	N
		25-59	N	Y	Y	N	N
		60+	N	Y	Y	N	N
	1987	1-4	Y ₁	Y	Y	Y	N
		5-9	Y ₁	Y	Y	Y	N
		10-14	N	Y	Y	Y	N
		15-24	N	Y	Y	Y	N
		25-29	N	Y	Y	N	N
		60+	N	Y ₃	Y	N	N
	1988	1-4	Y ₁	Y	Y	Y	N
		5-9	Y ₁	Y	Y	Y	N
		10-14	N	Y	Y	Y	N
		15-24	N	Y	Y	N	N
		25-59	N	Y	Y	N	N
		60+	N	Y	Y	N	N
	1989	1-4	Y ₁	Y	Y	Y	N
		5-9	Y ₁	Y	Y	Y	N
		10-14	N	Y	Y	Y	N
		15-24	N	Y	Y	Y	N
		25-59	N	Y	Y	N	N
		60+	N	Y ₂	Y ₃	N	N
	January – March 1990	1-4	Y ₁	Y	Y	Y	N
		5-9	Y ₁	Y	Y	Y	N
		10-14	N	Y	Y	Y	N
		15-24	N	Y	Y	Y	N
		25-59	N	Y	Y	N	N
		60+	N	Y ₂	Y ₃	N	N
	April – June 1990	1-4	Y ₁	Y	Y	Y	N
		5-9	Y ₁	Y	Y	Y	N
		10-14	N	Y	Y	Y	N
		15-24	N	Y	Y	Y	N
		25-59	N	Y	Y	Y	N
		60+	N	Y	Y	Y ₂	N

Y – (affirmative) means a Class Period Search is required

N – (negative) means a Class Period Search is not required

1 – Except for those less than 20 years of age at time of HCV diagnosis

2 – Pre-approval for this age group for 100+ units only

3 – Pre-approval for this age group for 200+ units only

PRE-APPROVAL TABLE 2 For use with female transfusion recipient							
Year of Birth							
		# of units transfused	1970+	1960-69	1945-59	1935-44	<1935
Year of Transfusion	1986	1-4	Y ₁	Y	Y	N	N
		5-9	Y ₁	Y	Y	N	N
		10-14	N	Y	Y	N	N
		15-24	N	Y	Y	N	N
		25-59	N	N	Y	N	N
		60+	N	N	N	N	N

	1987	1-4	Y ₁	Y	Y	N	N
		5-9	Y ₁	Y	Y	N	N
		10-14	N	Y	Y	N	N
		15-24	N	Y	Y	N	N
		25-29	N	Y	Y	N	N
		60+	N	N	N	N	N
	1988	1-4	Y ₁	Y	Y	N	N
		5-9	Y ₁	Y	Y	N	N
		10-14	N	Y	Y	N	N
		15-24	N	Y	Y	N	N
		25-59	N	Y	Y	N	N
		60+	N	N	N	N	N
	1989	1-4	Y ₁	Y	Y	Y	N
		5-9	Y ₁	Y	Y	N	N
		10-14	N	Y	Y	N	N
		15-24	N	Y	Y	N	N
		25-59	N	Y	Y	N	N
		60+	N	N	N	N	N
	January – March 1990	1-4	Y ₁	Y	Y	Y	N
		5-9	Y ₁	Y	Y	N	N
		10-14	N	Y	Y	N	N
		15-24	N	Y	Y	N	N
		25-59	N	Y	Y	N	N
		60+	N	N	N	N	N
	April – June 1990	1-4	Y ₁	Y	Y	Y	N
		5-9	Y ₁	Y	Y	Y	N
		10-14	N	Y	Y	Y	N
		15-24	N	Y	Y	Y	N
		25-59	N	Y	Y	Y	N
		60+	N	Y ₃	Y ₄	N	N

1544703