TBC Lookback Investigation:

Indication of Lookback:

- TBC QA initiates a Lookback of prior donations from a donor that now is confirmed positive for HIV, HCV, or Chagas.
- Lookback is required for all transfusable components previously prepared from the donor 12 months prior to the last negative test result.

Note:

 Due to the unavailability of a confirmatory test (RIBA) for HCV, lookbacks are being initiated by a second, licensed repeatedly reactive supplemental antibody test.

Process of Notification:

- <u>Notification Letter</u> and <u>Lookback Follow-up Form (5202PDFB)</u> are generated by TBC QA for each component in the lookback range.
- The letter and form (5202PDFB) is sent to the transfusion facility by certified mail, return receipt requested.
- The <u>Notification Letter</u> indicates the component, unit number and date component was shipped to the transfusion facility. TBC QA requests acknowledgement of receipt of this letter with a signature and date and to return this acknowledgment to TBC in the stamped, self-addressed envelope provided.
- The <u>Lookback Follow-up Form</u> (Sections I, II, and III) is completed by the transfusion facility and returned to TBC QA.
- Quarterly reviews by TBC QA of open lookback cases are performed and subsequent notification to the transfusion facility is made urging the completion of the lookback investigation.

Completion of Lookback Investigation:

- Transfusion facility assesses patient medical record availability.
- Transfusion facility makes an attempt to notify patient physician. If the physician declines to notify the patient, the transfusion facility conducts the patient notification in lieu of the physician.
- Transfusion facility completes <u>Lookback Follow-up Form (5202PDFB)</u> and returns form to TBC QA.

Note:

 Testing of the patient for HIV 1/2, HCV or Chagas antibodies can be done free of charge by TBC. Coordination with TBC is required to schedule and collect patient samples for testing.