

Questions for the Committee

1. With reference to Figure 1., if the Master Pool is NAT-Reactive and all individual donations are non-reactive,
 - a) (Option A): Should a single negative test on the individual donations be sufficient for release?
 - b) If not (Option B),
 - i) Should the individual donations be diluted and tested again using the same NAT method, or
 - ii) Should the individual donations be retested by an alternate NAT method (using a different technology or a second set of primers)?
2. With reference to Figure 2., if the Master Pool is NAT-Reactive but all Subpools (either archived or freshly pooled) are non-reactive, then, as shown in Figure 3.,
 - a) (Option A) Should all units be released ?If not,
 - b) (Option B) Should the Subpools be additionally tested by
 - i) dilution followed by re-test using the same NAT method, or
 - ii) retest by an alternate NAT method (using a different technology or a second set of primers) ?or
 - c) (Option C) Should individual donations be tested using the same NAT method?
3. With reference to Figure 2., if the Master Pool is NAT-Reactive and a Sub-pool is reactive, but the individual donations in that sub-pool all are non-reactive,
 - a) (Option A) Should all units be released?If not (Option B),
 - b) If the sub-pool was an archived pool from the construction of the original Master Pool
 - i) Should a “fresh” sub-pool be tested, with further testing only if the “fresh” sub-pool is reactive, or
 - ii) Should the individual donations be diluted and retested, or
 - iii) Should the individual donations be tested by an alternative NAT (using a different technology or a second set of primers)

or

- c) If the sub-pool was made “fresh”
 - i) Should the individual donations be diluted and tested again using the same NAT method, or
 - iii) Should the individual donations be retested by an alternate NAT method (using a different technology or a second set of primers) ?
- 4. Should replicate testing be recommended as a general way of confirming the status of initially reactive pools?
 - a. If so, how many replicates should be performed?
 - b. What is the maximum number of reactive replicate tests that will still allow the replicate testing to be scored as “Non-Reactive?”