**Facility Name and ID Number:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Accredited Activity(ies):**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Instructions:**

1) Test(s) Performed In-House: For each test, ensure that the kit is for donor testing (not patient testing). Enter the name of the test kit currently being used, the name of the manufacturer, and indicate if the test kit:

a) is for donor testing,

b) is FDA licensed, approved, or cleared,

b) has CE Mark, and/or

c) is approved by the Competent Authority where the facility resides.

2) If testing is performed by another facility, have the testing facility fill out the table as indicated above in Number 1. If that facility is AABB accredited, provide the laboratory’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

3) If your facility does not perform one or more of the required tests:

1. provide evidence that your facility questions donors about acute infection and travel history, specifically to areas where some of the viruses listed in table are endemic.
2. provide evidence of all associated deferral times defined/established for potential donors who have traveled to areas where some of the viruses listed in the table are endemic.
3. provide evidence from your Competent Authority indicating that testing is not required.

| **Test** | **Name of Kit** | **Manufacturer** | **Is the test for donor testing Y/N?** | **FDA licensed, approved, or cleared?** | **CE Mark?** | **Approved by the Competent Authority?** | **List the name of Laboratory That Performs Test** | **Eligible for a Variance** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **HBsAg****(Testing required for facilities in the United States Only)** |  |  |  |  |  |  |  | N/A |
| **Anti-HBc** |  |  |  |  |  |  |  | NO |
| **HBV DNA** |  |  |  |  |  |  |  | NO |
| **Anti-HCV** |  |  |  |  |  |  |  | NO |
| **HCV RNA** |  |  |  |  |  |  |  | NO |
| **Anti-HIV 1/2** |  |  |  |  |  |  |  | NO |
| **HIV-1 RNA** |  |  |  |  |  |  |  | NO |
| **Anti-HTLV I/II** |  |  |  |  |  |  |  | YES |
| **Syphilis** |  |  |  |  |  |  |  | NO |
| **CMV Total****or****IgG****IgM** |  |  |  |  |  |  |  | YES |
| ***Trypanosoma cruzi*** |  |  |  |  |  |  |  | YES |
| **WNV** |  |  |  |  |  |  |  | YES |
| **Babesia, spp (Testing required for facilities in the United States Only)** |  |  |  |  |  |  |  | N/A |

\**Please note that variance requests to infectious disease testing requirements will be considered only from international facilities where such testing is not required by their competent authority and only for the ID tests that are marked eligible for a variance in the chart above. US facilities must comply with all ID testing and a variance request will not be considered.*

Please provide the information requested in this document to the Accreditation and Quality Department (accreditation@aabb.org) when submitting your application.