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

**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, if the test kit is for donor testing, and indicate if the test kit: a) 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 that facility fill out the table as indicated above (if that facility is AABB accredited, simply list the lab’s name).**

**3) If your facility does not perform one or more of the required tests, please provide evidence that your facility questions donors concerning history of acute infection and travel history, specifically to areas where some of the viruses listed in table are endemic.**

**4) If your facility does not perform one or more of the required tests, please provide evidence of all associated deferral times set for potential donors who have traveled to areas where some of the viruses listed in the table are endemic.**

**5) If your facility does not perform one of the required tests, please 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** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **HBsAg** |  |  |  |  |  |  |  |
| **Anti-HBc** |  |  |  |  |  |  |  |
| **HBV DNA** |  |  |  |  |  |  |  |
| **Anti-HCV** |  |  |  |  |  |  |  |
| **HCV RNA** |  |  |  |  |  |  |  |
| **Anti-HIV 1/2** |  |  |  |  |  |  |  |
| **HIV-1 RNA** |  |  |  |  |  |  |  |
| **Anti-HTLV I/II** |  |  |  |  |  |  |  |
| **Syphilis** |  |  |  |  |  |  |  |
| **CMV Total****or****IgG****IgM** |  |  |  |  |  |  |  |
| ***Trypanosoma cruzi*** |  |  |  |  |  |  |  |
| **WNV** |  |  |  |  |  |  |  |
| **Babesia, spp (Facilities in the United States Only)** |  |  |  |  |  |  |  |

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