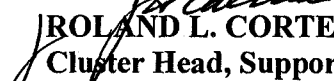


Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

DEPARTMENT CIRCULAR

No. 2013 - 0132

TO : All CHD Directors, Chief of Hospitals/Medical Centers/Sanitaria, Regional Blood Program Coordinators, Blood Bank Heads, Lead Blood Service Facility, Provincial Health Officers and All Others Concerned

FROM :  **ROLAND L. CORTEZ, MD, MHA, CESO IV, CEO VI**
Cluster Head, Support to Service Delivery Technical Cluster I

SUBJECT: National Council for Blood Services – Technical Committee Recommendations, Strategies, Methodologies and Algorithms for Testing Blood Units for Transfusion Transmissible Infection

DATE: March 19, 2013

In order to establish a reliable, effective and appropriate testing of blood units and to implement quality-assured testing for Transfusion Transmissible Infection (TTI), the National Council for Blood Services - Technical Committee chaired by Dr. Elizabeth Y. Arcellana-Nuqui recommends the following testing strategies, methodologies and testing algorithms, mainly aligned with WHO Recommendations on Screening Donated Blood for Transfusion-Transmissible Infections, to be adopted by all Blood Service Facilities.

Please be guided accordingly.

Strategies and Recommendations:

1. All whole blood and apheresis donations shall be tested for evidence of TTI prior to release for cross-matching and transfusion.
2. Testing of all blood donations shall be mandatory for the following infections and shall be run simultaneously or in parallel using the following serological markers:
 - HIV-1 and HIV-2: either a combination of HIV antigen-antibody or HIV antibodies
 - Hepatitis B: Hepatitis B surface antigen (HBsAg)
 - Hepatitis C: either a combination of HCV antigen-antibody or HCV antibodies
 - Syphilis (*Treponema pallidum*): screening for specific treponemal antibodies.

- Malaria: screening for antigen or antibody or demonstration of the parasite in a thick and thin blood smear
3. All testing of blood donations for TTIs shall be carried out only on samples taken from the blood unit and in a quality controlled environment.
 4. If found initially reactive to any of the TTIs and the test is valid, the blood unit shall be referred to National Voluntary Blood Services Program – National Reference Laboratory (NVBSP-NRL) for confirmatory testing. If the testing is performed following strict guidelines and under quality -assured conditions, there is no need to repeat test in duplicate. Please refer to the new testing algorithm.
 5. Only licensed BSFs shall be allowed to test blood for the five (5) mandatory TTIs. Where feasible, blood testing shall be centralized in identified Lead Blood Service Facilities to achieve uniformity of standards, increased safety and economies of scale.
 6. The minimum evaluated sensitivity and specificity levels of all assays used for blood screening shall be as high as possible and preferably not less than 99.5% with Certificate of Product Registration from Food and Drug Administration (FDA) and proof of Kit Evaluation from STD AIDS Cooperative Central Laboratory (SACCL). Only reagent kits with current and valid certificates of product registration and SACCL evaluation shall be used in screening blood units for TTIs.
 7. Quality-assured testing of all donations using serology shall be in place before testing strategies utilizing nucleic acid testing are considered.
 8. Only blood and blood components that are nonreactive in all five (5) mandatory TTIs shall be released for cross-matching and transfusion.
 9. All blood unit tested reactive to TTI shall be properly labelled and stored separately until discarded safely and appropriately or sent to NVBSP-NRL for confirmatory testing. Furthermore, blood units tested reactive for HBsAG under the test kits and criteria listed under Department Circular 2012-0198 shall no longer be sent to NVBSP-NRL for further testing.
 10. Blood units tested reactive to syphilis shall not be referred nor sent to NVBSP-NRL for further testing.
 11. Blood unit tested reactive by methods that do not conform to the guidelines herein shall not be accepted for further testing by the NVBSP-NRL
 12. Blood unit shall not be retested by transfusing facility or by other BSF provided the source BSF tested the blood units in conformity with the guidelines herein, and that the retesting BSF should also meet the guidelines herein.
 13. All staff performing TTI testing shall have undergone training and passed proficiency testing offered by the NVBSP-NRL or SACCL. Only trained and proficient staff shall perform testing of donated blood units for TTIs.
Blood Service Facilities which are found to be using unlicensed or unregistered testing kits shall have their license to operate suspended or revoked by the Bureau of Health Facility Services (BHFS).

Methodology:

1. Human Immunodeficiency Virus:

- Testing shall be performed using a highly sensitive and specific anti-HIV-1 + anti-HIV-2 immunoassay or HIV combination antigen-antibody immunoassay (EIA/CLIA). The assay shall be capable of detecting subtypes specific to the country or region.

TTI	Testing marker	Recommended Assay	Comments
HIV	Anti-HIV (1,2,O) or Combination of Anti-HIV (1,2, O) and HIV p24 antigen	Immunoassay	Testing for HIV antibody is recommended as minimum standard for blood safety but at present, the most sensitive HIV serological assay is a combined detection of antigen (p24 antigen) and antibody (anti-HIV-1 and -2). These assays are considered to be the most effective for the serological testing of donated blood.

2. Hepatitis B

- Testing shall be performed using a highly sensitive and specific HBsAg immunoassay (EIA/CLIA).
- Testing for anti-HBc and ALT is not recommended.

TTI	Testing marker	Recommended Assay	Comments
Hepatitis B	HBsAg	Immunoassay	HBsAg is the first serological marker of HBV and its determination is recommended as minimum standard for blood safety

3. Hepatitis C

- Testing shall be performed using a highly sensitive and specific HCV antibody immunoassay or a combination HCV antigen-antibody immunoassay (EIA/CLIA). The assay shall be capable of detecting genotypes specific to the country or region.

TTI	Testing marker	Recommended Assay	Comments
Hepatitis C	Anti-HCV or Combination of Anti-HCV and HCV Antigen	Immunoassay	The most sensitive and effective for the HCV serological testing of blood donation is a combined detection of antigen and antibody however due to limited number of commercially available assays, testing for HCV antibody is recommended as minimum standard for blood safety.

4. Syphilis

- Testing shall be performed using a highly sensitive and specific test for treponemal antibodies: either TPHA or enzyme immunoassay.

TTI	Testing marker	Recommended Assay	Comments
Syphilis	Antibody to treponema pallidum	Particle Agglutination Immunoassay	Testing for specific treponemal antibody is recommended as minimum standard for blood safety.

5. Malaria

- All donations shall be tested for evidence of malarial antigen using a highly sensitive enzyme immunoassay or for parasitemia using thick blood films.

TTI	Testing marker	Recommended Assay	Comments
Malaria	Malarial antigen or antibody Presence of malarial parasite	Immunoassay EIA Nonmicroscopic Rapid Test Smear Microscopy	High quality, sensitive malaria antigen assay may be better able to identify parasitemic donations, including those with much lower levels of parasites than are reliably detectable by thick film, however direct detection of parasite by thick and thin smear is still recommended as minimum standard for blood safety.