

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Donor Notification of Significant Findings		
Applies To:	All Blood Bank Staff		
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1. PURPOSE:

- 1.1 Developing a system for donor notification of significant findings detected during screening or after performing laboratory testing.

2. DEFINITONS:

- 2.1 N/A

3. POLICY:

- 3.1 Events requiring official donor notification have to be defined.
- 3.2 Proper education, counselling, and referral for donors with significant findings.
- 3.3 Acknowledgment of the notification is documented within eight weeks of donation.

4. PROCEDURE:

- 4.1 Events requiring official donor notification:
 - 4.1.1 Donors who have confirmed positive Transfusion-Transmitted Disease (TTD) test results:
 - 4.1.1.1 Supervisor of blood bank or his deputy must notify the Preventive medicine department/health authorities with all the confirmed TTD positive test results.
 - 4.1.1.2 Notify all donors who have confirmed positive TTD results of any medically significant abnormality detected as a result of laboratory testing or recipient follow-up.
 - 4.1.2 Donors who have unusual red cell serology.
 - 4.1.3 Donors who have rare blood groups.
- 4.2 Notification of significant findings detected during screening:
 - 4.2.1 Donors showed significant symptoms and signs of blood born transmitted diseases during donor selection should be informed by the staff in charge that he might have the infection and referred to a physician through referring him to Preventive medicine department.
- 4.3 Notification of significant findings detected after performing laboratory testing:
 - 4.3.1 As all TTD laboratory testing is done in Hafr Al Batin Central Lab And Blood Bank, MCH blood bank follows the policies and procedures of the Central Lab And Blood Bank regarding testing and its confirmation as required.
 - 4.3.2 Because all transfusion-transmitted infectious agents are of low prevalence in the asymptomatic donor population. The predictive value of a positive screening test will be low. Thus, since a positive screening result will usually be a false positive result. It is essential that screening tests be followed with a more specific supplementary or confirmatory test (NAT) prior to notifying donors of their test results .
 - 4.3.3 Results of supplemental testing may indicate that the donor is infected, is false positive and not infected, or may be inconclusive (indeterminate).
 - 4.3.4 Donors who have confirmed positive TTD test results:
 - 4.3.4.1 The basic principles of donor notification for confirmed seropositive donors involve providing information to the donor accurately, confidentially, as quickly as possible

(maximum within eight weeks, and in a manner that alleviates anxiety and promotes understanding).

4.3.4.2 If blood bank technician/ specialist receives confirmed positive TTD result, he writes report "Donor with Positive TTD Tests Report", signed by lab director, with full donor information, name- ID- telephone number- address.

4.3.4.3 This report is sent to Preventive medicine department. Keep a copy of this document in the specified file.

4.3.4.4 A staff of the Preventive medicine department is assigned to notify the donor about his positive result and arranges with him for the different measures taken in this case. Donor recall form is used to document donor contact.

4.3.4.5 Notification of the donor occurring at a face to face interview after calling him by phone to come to blood bank and meet the physician, specialist or supervisor.

4.3.4.6 Seropositive donors need to be informed of:

- 4.3.4.6.1 Their ineligibility as donors.
- 4.3.4.6.2 The medical significance of their test result.
- 4.3.4.6.3 The possible modes of transmission of the agent and how to prevent.
- 4.3.4.6.4 The possible disclosure of the result to health authorities, including when and how this may happen and to whom.

4.3.4.7 Acknowledgment of the notification is documented in the donor notification form that includes the consent of the donor that he was informed within eight weeks of donation.

4.3.4.8 The donor is referred to a physician through referring him to Preventive medicine department.

4.3.4.9 It is recommended that the information contained in such notification inform donor that:

- 4.3.4.9.1 A positive test result could indicate that he recently developed the infection or that he may have chronic infection.
- 4.3.4.9.2 He is likely to be infectious to others.
- 4.3.4.9.3 There is safe and effective vaccine that can prevent the spread of HBV to their household contacts and sexual partners.
- 4.3.4.9.4 He is ineligible for future donation.

4.3.4.10 Information For Donors With a Positive Test are used:

- 4.3.4.10.1 For Hbc Ab positive results
- 4.3.4.10.2 For HBsAg positive results
- 4.3.4.10.3 For HCV Ab positive results
- 4.3.4.10.4 For HIV Ab positive results
- 4.3.4.10.5 For HTLV Ab positive results
- 4.3.4.10.6 For Syphilis Ab positive results
- 4.3.4.10.7 For HBV DNA (by NAT) positive results

4.3.5 Donors with reactive or inconclusive TTD test results:

- 4.3.5.1 Because notification of indeterminate donors carries uncertainty about their infection status, The counselling process is difficult and often results in donor anxiety.
- 4.3.5.2 They should be informed and counselled about the probability of need to give a new blood sample to confirm their test results, in accordance with the confirmatory testing strategy (of Hafr Al Batin Central Lab and Blood Bank).

4.3.6 Donors who have unusual red cell serology or rare blood groups:

- 4.3.6.1 They are given (by blood bank technician/specialist) information about:

 - 4.3.6.1. The antibodies or blood group.
 - 4.3.6.1. The implications for future blood donations.
 - 4.3.6.1. The importance of carrying this information personally at all times in case they ever need a blood transfusion.
 - 4.3.6.1. Opportunities for enrolling on the rare blood donor panel.
 - 4.3.6.1. The importance of healthy lifestyles and regular blood donation.
 - 4.3.6.1. Keep a File for donors' unusual red cell serology or rare blood groups.

5. MATERIALS AND EQUIPMENT:

5.1 Records and forms:

- 5.1.1 Donor with Positive and negative TTD Tests Report & Hematos system of blood bank
- 5.1.2 Donor notification form
- 5.1.3 NAT and Serology result record

6. RESPONSIBILITIES:

- 6.1 Supervisor of blood bank technicians or his deputy must notify the Preventive medicine department/health authorities with all the confirmed TTD positive test results.
- 6.2 Requesting a new sample from donors for confirmatory tests is the responsibility of blood bank staff in the donor room.
- 6.3 Preventive medicine department staff is responsible for notifying donors with confirmed positive TTD results and donor referral.
- 6.4 Blood bank doctor, supervisor, or specialist are responsible for donor counselling.

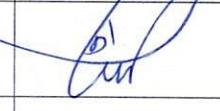
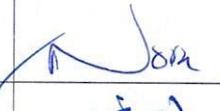
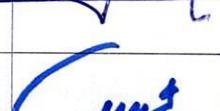
7. APPENDICES:

- 7.1 N/A

8. REFERENCES:

- 8.1 The Unified Practical Procedure Manual For Blood Banks In The Arab Countries, 1434-2013.
- 8.2 The Standard Policy For Blood Banks In The Kingdom Of Saudi Arabia, 1st edition, 1435-2014.
- 8.3 National Standards For Clinical laboratories and Blood Banks, 1st edition, 2015.
- 8.4 AABB Technical manual, 18th edition, 2014.
- 8.5 AABB Standards for Blood Banks and Transfusion Services, 30th edition, 2016.
- 8.6 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA

9. APPROVALS:

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