



MANAGEMENT OF SEROCONVERTED PATIENT(S) HOSPITAL KUALA LUMPUR

MANAGEMENT OF SEROCONVERTED PATIENT(S)

1.0 Objective

Providing safe and adequate blood is a vital component of healthcare delivery system. In addition to that, all processes involved in the blood transfusion chain must be of quality which will result in the best patient care.

2.0 Scope

The management of seroconvert donors and recipients is an important obligation of both the blood transfusion service and the clinicians who ordered the transfusion.

3.0 Reference

- i. Transfusion Practice Guidelines for Clinical and Laboratory Personnel, National Blood Centre, Ministry of Health Malaysia, 4TH EDITION 2016
- ii. Joint UKBTS Professional Advisory Committee : Look Back and Trace Back January 2015
- iii. Residual Transmission Risk and NAT Prevalence for PDN and Central region from 2008-2018 data

4.0 Definition

4.1 Haemovigilance - is a surveillance programme covering adverse events occurring during the entire blood transfusion chain from the donation of blood to the follow-up of patients receiving transfusion. The ultimate goal of haemovigilance is to improve patient and donor safety through the detection, reporting, analysis of information on unexpected or undesirable effects, and implementation of corrective and preventive actions.

4.2 Recipient Counselling - The team involved in counselling recipients should include at least the treating specialist/consultant and may include a transfusion medicine specialist.

4.3 Seroconverted donor - is a donor who is confirmed positive for a particular TTI in his current donation but was negative in the previous donation.

- 4.4 Seroconverted recipient** - is a recipient who is confirmed positive for a particular TTI marker(s) after receiving blood transfusion, but who was negative for that infection prior to the transfusion.
- 4.5 Window period** - The time interval that elapses between infection and the appearance of detectable antibodies or antigens by the laboratory testing methods.
- 4.6 Lookback** - Tracing all blood component from a potentially infectious donations and the relevant recipients. This will include previous donations that may have been given during the window period.
- 4.7 Recall** - Withdrawal of in-date blood components involved in the lookback procedure which may still be in the inventory.
- 4.8 Transfusion transmitted infections (TTI)** – infection agents that can be transmitted through transfusion of blood and blood products
- 4.9 Residual risk** can be defined as the probability of collecting a donation from an asymptomatic viraemic donor infected with one of these blood borne viruses not being detected by the routine screening assays. The estimated residual risk / residual transmission risk for each transfusion transmitted infection is as follows:

TYPE OF INFECTION	RESIDUAL RISK PER MILLION DONATION
Hepatitis B	6.78
Hepatitis C	0.23
HIV	1.91

- 4.10 Nuclei Acid Test screening** began in November 2007 in the central region and expanded nationwide in 2019. By January 2021, 100% of donated samples had successfully undergone NAT screening. Therefore, in cases where the implicated donation(s) was not screened with NAT testing, lookbacks and recall procedure shall be done for the last negative donation and donation(s) in the six months period to the last negative donation.

The average window period is based on the current method used for both tests. The average window period will change according to the method used.

5.0

TYPE OF INFECTION	TEST FOR RECIPIENT
Syphilis	RPR TPPA
Hepatitis B	HBsAg HBsAg Neutralization (Other supportive test for e.g. Molecular)
Hepatitis C	AntiHCV Line Immunoassay (Other supportive test for e.g. Molecular)
HIV	HIV 1 & 2 (Antigen- Antibody 1 &2) Line Immunoassay (Other supportive test for e.g. Molecular)

6.0 Abbreviation

TTI	- Transfusion Transmitted Infection
HIV	- Human Immunodeficiency Virus
WP	- Window Period
NAT	- Nuclei Acid Test
RPR	- Rapid Plasma Reagin
TPPA	- Treponema Pallidum Particle Agglutination Assay
HBsAg	- Hepatitis B Surface Antigen
AntiHCV	- Antibody To Hepatitis C Virus
HKL	- Hospital Kuala Lumpur
COD	- Cause of Death

MANAGEMENT OF SEROCONVERTED DONOR(S), HOSPITAL KUALA LUMPUR

Num	Action	Person In Charge
1.	Receive notification letter from Pusat Darah Negara that a donor(s) has been seroconverted and a lookback and recall procedure has been initiated.	Hospital Director
2.	Hospital Director to assign the letter to the attention of the Head of Department(s).	Hospital Director
3.	Head of Department(s) shall minute and assign the letter to the department liaison.	Head of Department Department Liaison Officer
4.	Retrieve patient(s) file and baseline results if available.	Medical Record Officer Department Liaison Officer
5.	Contact / Trace all involved patient(s). Schedule appointment date for First Patient Counselling session and blood sample testing at HKL.(if able to contact patient(s))	Doctor / Specialist
6.	If patient(s) cannot be found, enlist police's help to trace patient.	Department Liaison Officer / Doctor / Jabatan Kerja Sosial Perubatan / Police
7.	In the event that the recipient(s) has passed away, contact next of kin (if number available) to obtain cause of death. Inform Department Liaison Officer / Doctor.	
8.	If unable to trace patient(s) or next of kin from hospital data and if police is unable to trace patient(s), send an email / letter to JKSP requesting assistance to identify patient(s) family tree in order to contact patient(s).	
9.	Once patient(s) found, schedule appointment date for First Counselling session and blood sample testing at HKL.	Department Liaison Officer / Doctor
10.	<u>First counselling :</u> i. Inform the recipient(s) the reason for consultation.	Department Liaison Officer / Doctor

ii. Inform and explain that the blood or blood component transfused was from a donor who recently seroconverted. As a precautionary measure, the recipient(s) needs to be tested to ascertain whether he or she is infected following the transfusion of a possible window period donation.

iii. Explain that “window period” IS NOT a laboratory error.

iv. Average window period for each infection:

Type of infection	WP serologic testing	WP NAT testing
Hepatitis B	36-38 days	15-17 days
Hepatitis C	58-60 days	2-3 days
HIV	15-16 days	4-5 days

v. Assess the risk factors of the recipient(s) with respect to the TTI concerned. Try to identify risk factors other than blood transfusion.

vi. Explain about the TTI concerned, including its mode of transmission and potential complications.

vii. Explain about tests available and the interpretation of the results.

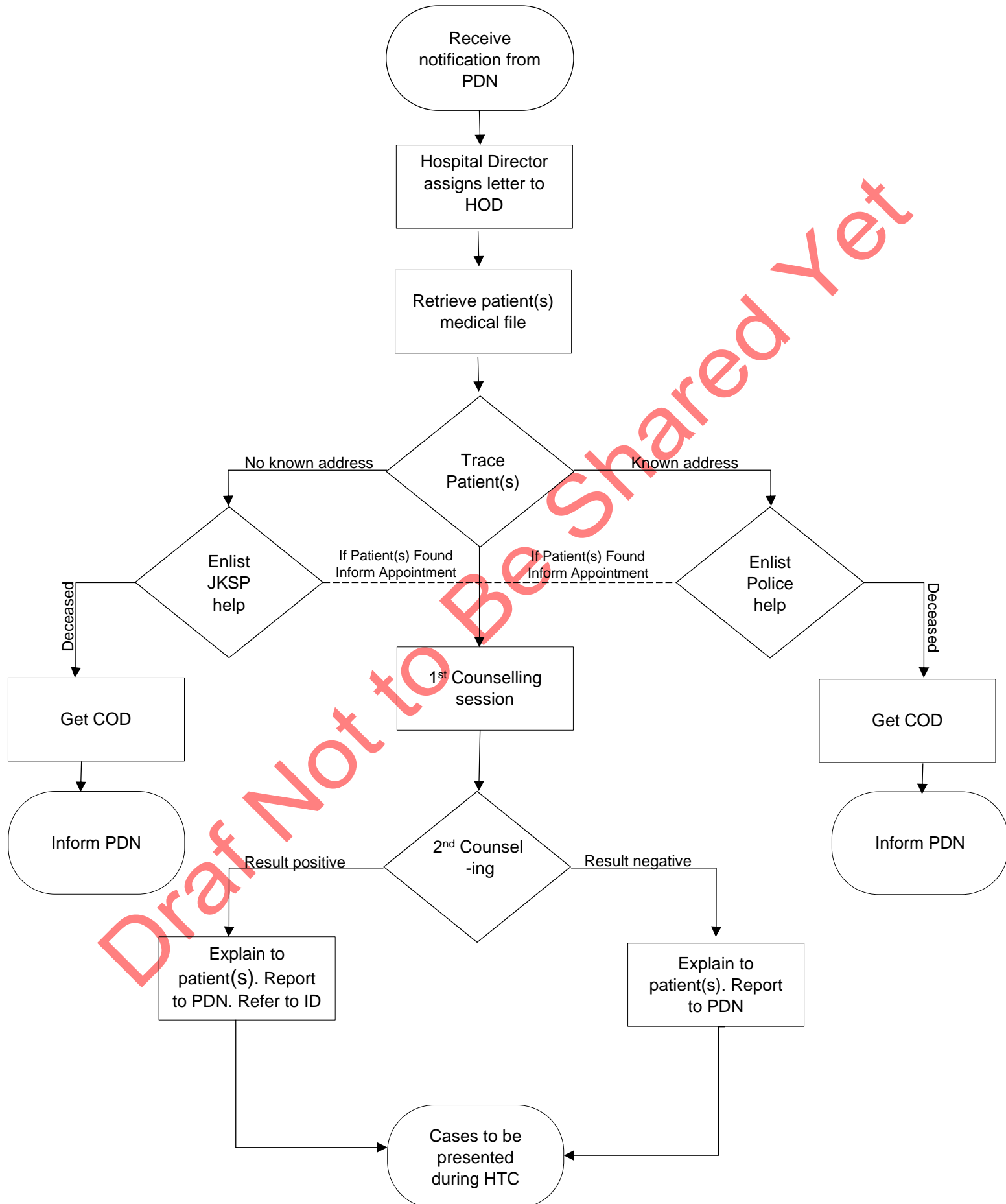
viii. Take samples of blood for the implicated infection, and reassure the recipient(s) that the probability of being infected through transfusion is low.

	<p>ix. Inform about the precautions to be taken while waiting for the test results. This is to prevent potential transmission from the recipient(s) to others.</p> <p>x. Discuss with the recipient(s) the probability of the test outcome.</p> <p>Set appointment date for Second Counselling.</p>	
11.	<p>Second Counselling session :</p> <p>i. Positive result</p> <ul style="list-style-type: none"> • Inform the recipient(s) and explain. • Further assess the risk factors other than blood transfusion. If none, explain to blood him or she received was tested negative at the time of donation. • Report transfusion-related adverse event to PDN using form BTS/ HV/3/2016 • Reassure and discuss about the treatment options. • Refer the donor(s) to an infectious disease physician. <p>ii. Negative result</p> <ul style="list-style-type: none"> • Inform the recipient(s) and explain. • Reassure the recipient(s). • If necessary, retest after 6 months post transfusion of implicated donation or implement any follow-up. 	Doctor / Specialist
12.	Notify the result to PDN and provide a copy of PDN initial letter together with recipient(s) result.	Department liaison officer

13.	Refer patient(s) to Infectious Disease Physician for further management.	Infectious Disease Physician
14.	All seroconvert case(s) to be discussed in Hospital Transfusion Committee Meeting 6 monthly meeting.	Hospital Transfusion Committee

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WORK FLOW FOR SEROCONVERTED DONOR AT HOSPITAL KUALA LUMPUR LEVEL

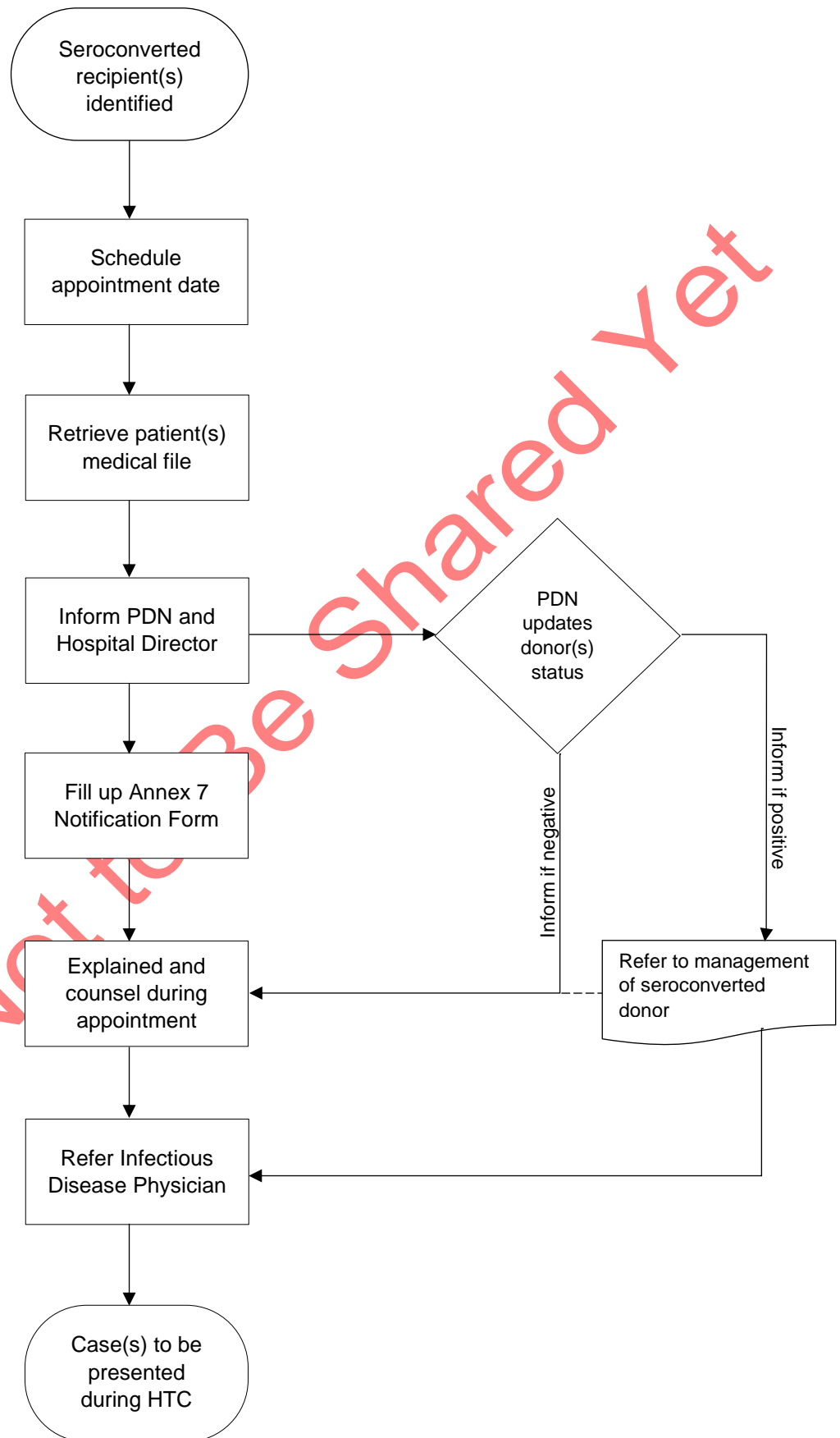


MANAGEMENT OF SEROCONVERTED RECIPIENT(S)

Num	Action	Person In Charge
1.	Seroconverted recipient identified. Schedule appointment date.	Doctor / Specialist
2.	<p>Retrieve patient/s file and to identify information below :</p> <ul style="list-style-type: none"> i. Name of the recipient(s) ii. I.C number (old or new)/ passport number iii. Diagnosis iv. Date of latest infective screening(s) tested non-reactive v. Date of infective screening(s) tested confirm positive vi. All transfusion history (date of transfusion, place of transfusion, type of blood component transfused and blood component barcode number) vii. All available infective screening result(s) of the recipient and date of test done 	<p>Doctor / Specialist Department liaison officer</p>
3.	<p>Department liaison officer to send formal notification letter to Hospital Director and PDN, and to include information as above.</p> <p>Inform blood bank to initiate "look back and recall.</p>	<p>Doctor / Specialist Department liaison officer</p>
4.	Notify and fill up form Annex 7 NOTIFICATION FORM, <i>NOTIFIKASI PENYAKIT BERJANGKIT YANG PERLU DILAPORKAN</i> .	<p>Doctor / Specialist Department liaison officer</p>
5.	<p>PDN to investigate status of donor(s) and inform back to department liaison officer.</p> <ul style="list-style-type: none"> i. If donor(s) retesting is negative, to give feedback to clinician. ii. If donor confirmed positive, to counsel donor, notify physician and refer to infectious disease physician. 	PDN
6.	<p>Seroconvert Recipient(s) Counselling</p> <ul style="list-style-type: none"> i. Recipients of a transfusion may develop HIV, Hepatitis B, Hepatitis C, Syphilis infection or other possible TTI agent infection resulting from : 	Doctor / Specialist

	<p>a) Transfusion of blood that was donated within the window period of the infection, or</p> <p>b) Other sources not related to blood transfusion.</p> <p>ii. If there are no other risk factors, inform the recipient that the blood he or she received was tested negative at the time of donation. Explain about 'window period' donation and it WAS NOT a lab error.</p> <p>iii. Explain about the implicated TTI, including its mode of transmission and potential complications.</p> <p>iv. Discuss options in treatment.</p> <p>v. Inform about the precautions to be taken to prevent potential transmission from the recipient to others.</p>	
7.	Refer the recipient(s) to an infectious disease physician.	Doctor / Specialist
8.	All seroconvert cases to be discussed in Hospital Transfusion Committee Meeting 6 monthly meeting.	Doctor / Specialist

WORK FLOW FOR SEROCONVERTED RECIPIENT AT HOSPITAL KUALA LUMPUR LEVEL





Rujukan kami : () HKL /
Tarikh :

Ketua Jabatan
Jabatan Kerja Sosial Perubatan
Hospital Kuala Lumpur

YBrs Tuan ,

MEMOHON BANTUAN MENGESAN STATUS PESAKIT ATAU *FAMILY TREE*

Dengan segala hormatnya merujuk kepada perkara di atas.

2. Untuk makluman YBrs Tuan, pihak kami sedang dalam usaha untuk menghubungi pesakit and warisnya yang seperti di bawah untuk hadir ke temujanji saringan kesihatan yang mustahak.

Nama Pesakit :

Nom. Kad Pengenalan / Passport :

Alamat rumah :

Nom. Telefon :

Diagnosis :

Nama Waris Pesakit :

Alamat rumah :

Nom. Telefon :

3. Pihak kami telah berkali – kali cuba menghubungi pesakit dan warisnya melalui nombor telefon yang telah didaftarkan namun tiada jawapan. Pihak kami juga telah memohon bantuan pihak polis untuk memaklumkan tarikh temujanji kepada pesakit berdasarkan pada alamat yang didaftarkan namun demikian didapati pesakit tidak tinggal disitu lagi.

4. Sehubungan dengan itu, pihak kami ingin memohon bantuan dan jasa baik pihak YBrs Tuan dalam usaha mengenalpasti alamat terakhir pesakit, warisnya atau pun *family tree* untuk memudahkan pihak kami menyampaikan maklumat yang mustahak ini.

5. Kerjasama dan perhatian daripada pihak YBrs Tuan amatlah dihargai dan didahului dengan ucapan ribuan terima kasih. Sebarang pertanyaan lanjut, sila hubungi NAMA PEGAWAI di sambungan 03 – 2615 XXXX.

Sekian.

" MALAYSIA MADANI "

"BERKHIDMAT UNTUK NEGARA"

(NAMA KETUA JAB. / CAW / BHG / UNIT)(MPM : XXXXX)

Jab. / Caw / Bhg / Unit

Hospital Kuala Lumpur

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E-mail : emel rasmi

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Tarikh :

Pengarah
Pusat Darah Negara
Jalan Tun Razak
50400 Kuala Lumpur

YBhg Datuk / Dato' / Datin / Tuan / Puan,

SEROCONVERTED RECIPIENT – LOOKBACK & RECALL PROCEDURE

Dengan segala hormatnya perkara diatas adalah dirujuk.

Untuk makluman pihak YBhg Datuk / Dato' / Datin / Tuan / Puan pihak kami telah mengenalpasti satu pesakit yang dikategorikan sebagai **seroconverted recipient**.

2. Berikut adalah butiran mengenai pesakit tersebut :

Nama Penerima	:
Nom. Kad Pengenalan / Passport	:
Diagnosis	:
Tarikh terakhir ujian saringan berjangkit yang tidak reaktif	: Date of latest non-reactive infective screening test
Tarikh saringan disahkan infekitif positif	:
Sejarah transfusi	:
Tarikh transfusi	:
Lokasi transfusi	:
Jenis komponen darah yang ditransfusi	:
Nom. Kod Bar. Komponen Darah	:

3. Bersama surat ini disertakan sesalinan keputusan laporan yang berkenaan untuk tindakan pihak YBhg Datuk / Dato' / Datin / Tuan / Puan **(lampiran)**. Kerjasama dan perhatian daripada pihak YBhg Datuk / Dato' / Datin / Tuan / Puan amatlah dihargai dan didahului dengan ucapan ribuan terima kasih. Sebarang pertanyaan lanjut, sila hubungi NAMA PEGAWAI di sambungan 03 – 2615 XXXX.

Sekian.

" MALAYSIA MADANI "

"BERKHIDMAT UNTUK NEGARA"

(DATIN PADUKA DR ROHANA BT JOHAN)(MPM : 29304)

Pengarah

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YBhg Datuk / Dato' / Datin / Tuan / Puan,

**MAKLUMBALAS MENGENAI KEPUTUSAN UJIAN SARINGAN DARAH PESAKIT
BERNAMA (NOM. K/P)**

Dengan segala hormatnya saya merujuk kepada surat bertajuk **TAJUK SURAT DARI PDN**, bernombor rujukan (xx) xxxxxxxxxxxxxxxxxxxxxxxx bertarikh xxxxxxxxxxxxxxxx berkaitan perkara di atas.

2. Untuk makluman YBhg Datuk / Dato' / Datin / Tuan / Puan, susulan daripada siasatan saringan darah didapati pesakit tersebut disahkan **SEROCONVERT POSTIF**. Pihak kami telah menasihatkan pada pesakit mengenai keadaannya serta langkah-langkah yang perlu diambil untuk menjaga kesihatan mereka. Pesakit juga telah dirujuk kepada Pakar Infectious Disease untuk tindakan yang sewajarnya.

3. Bersama surat ini disertakan sesalinan keputusan laporan yang berkenaan untuk tindakan pihak YBhg Datuk / Dato' / Datin / Tuan / Puan (**lampiran**). Kerjasama dan perhatian daripada pihak YBhg Datuk / Dato' / Datin / Tuan / Puan amatlah dihargai dan didahului dengan ucapan ribuan terima kasih. Sebarang pertanyaan lanjut, sila hubungi NAMA PEGAWAI di sambungan 03 – 2615 XXXX.

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YBhg Datuk / Dato' / Datin / Tuan / Puan,

**MAKLUMBALAS MENGENAI KEPUTUSAN UJIAN SARINGAN DARAH PESAKIT
BERNAMA (NOM. K/P)**

Dengan segala hormatnya saya merujuk kepada surat bertajuk **TAJUK SURAT DARI PDN**, bernombor rujukan (xx) xxxxxxxxxxxxxxxxxxxxxxxx bertarikh xxxxxxxxxxxxxxxx berkaitan perkara di atas.

2. Untuk makluman YBhg Datuk / Dato' / Datin / Tuan / Puan, susulan daripada siasatan saringan darah didapati pesakit tersebut disahkan **SEROCONVERT NEGATIVE**. Pihak kami telah memaklumkan pada pesakit mengenai keputusan ujian saringannya. Pesakit juga diberi tarikh temujanji enam bulan dari sekarang untuk melakukan ujian saringan berkala.

3. Bersama surat ini disertakan sesalinan keputusan laporan yang berkenaan untuk tindakan pihak YBhg Datuk / Dato' / Datin / Tuan / Puan (**lampiran**). Kerjasama dan perhatian daripada pihak YBhg Datuk / Dato' / Datin / Tuan / Puan amatlah dihargai dan didahului dengan ucapan ribuan terima kasih. Sebarang pertanyaan lanjut, sila hubungi NAMA PEGAWAI di sambungan 03 – 2615 XXXX.

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JALAN PAHANG

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Rujukan kami : () HKL /
Tarikh :

Pengarah
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Jalan Tun Razak
50400 Kuala Lumpur

YBhg Datuk / Dato' / Datin / Tuan / Puan,

MAKLUMBALAS MENGENAI STATUS PESAKIT BERNAMA (NOM. K/P)

Dengan segala hormatnya saya merujuk kepada surat bertajuk **TAJUK SURAT DARI PDN**, bernombor rujukan (xx) xxxxxxxxxxxxxxxxxxxxxxxx bertarikh xxxxxxxxxxxxxxxx berkaitan perkara di atas.

2. Untuk makluman YBhg Datuk / Dato' / Datin / Tuan / Puan, pihak kami telah berusaha untuk mengenalpasti alamat terakhir pesakit namun didapati bahawa pesakit tersebut telah meninggal dunia. Walau bagaimana pun pihak kami berjaya mendapatkan punca kematian pesakit tersebut.

3. Bersama surat ini disertakan sesalinan keputusan laporan yang berkenaan untuk tindakan pihak YBhg Datuk / Dato' / Datin / Tuan / Puan (**lampiran**). Kerjasama dan perhatian daripada pihak YBhg Datuk / Dato' / Datin / Tuan / Puan amatlah dihargai dan didahului dengan ucapan ribuan terima kasih. Sebarang pertanyaan lanjut, sila hubungi NAMA PEGAWAI di sambungan 03 – 2615 XXXX.

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