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Implementation: To be determined by each Service

## Change Notification UK National Blood Services No. 01 - 2022

# Coronavirus Infection and Convalescent Plasma

These changes apply to the Whole Blood and Component Donor Selection Guidelines.

Please amend the following entries as shown.

## 38.1 Coronavirus Infection (COVID-19)

<i>Includes:</i>	<p><del>SARS (Severe Acute Respiratory Syndrome)</del>  <del>MERS (Middle Eastern Respiratory Syndrome)</del>          COVID-19 disease (due to infection with SARS-CoV-2 virus, previously known as Novel Coronavirus or 2019-nCoV)</p>
<i>Definitions:</i>	<p><b>Symptoms of Coronavirus infection COVID-19 include:</b></p> <ul style="list-style-type: none"> <li>• Fever</li> <li>• New persistent cough</li> <li>• Loss, or change in sense of smell and/or taste</li> </ul> <p><b>Testing:</b> PCR (polymerase chain reaction) and rapid lateral flow tests (LFTs), usually by throat and/or nose swab, to detect the presence of SARS-CoV-2. This does not include testing for antibodies to SARS-CoV-2.</p> <p><b>Confirmed Infection:</b> The donor has had a positive test for the presence of Coronavirus SARS-COV-2 (Coronavirus) <del>usually by a throat and nose swab This does not include testing for antibodies to Coronavirus.</del></p> <p><b>Recovery from Coronavirus infection COVID-19:</b> Donors can be considered to have recovered if they:</p> <ul style="list-style-type: none"> <li>• Are generally well and back to normal activities</li> <li>• Do not have continuing fatigue which affects daily activities</li> <li>• Do not have a fever</li> <li>• Do not have respiratory symptoms (except for a persistent mild cough)</li> <li>• Are not experiencing cardiac symptoms (e.g. chest pain, palpitations)</li> <li>• Are not experiencing any other symptoms e.g. peripheral neurological symptoms in upper or lower limbs, central neurological symptoms such as headache, dizziness.</li> </ul> <p>Some individuals may have a mild cough, or reduced sense of smell or taste, for some weeks after resolution of their infection but they can be considered as recovered for the purposes of blood and component donation.</p>

<b>1. Affected Individual</b>	
<i>Includes:</i>	Donors who have had confirmed, or suspected, <b>COVID-19 Coronavirus infection</b> and donors who report any of the symptoms listed above.
<i>Obligatory:</i>	Must not donate.
<i>Discretionary</i> :	<p>a) If the donor had <b>Coronavirus</b> symptoms of <b>COVID-19</b> and</p> <ul style="list-style-type: none"> <li>• the donor has had a positive test for SARS-COV-2 (Coronavirus), and</li> <li>• any period of isolation has finished, and</li> <li>• no further testing is required, and</li> <li>• it is at least seven days from the resolution of symptoms,</li> </ul> <p>accept <del>has tested positive for the presence of Coronavirus and it is at least 28 days from resolution of symptoms, accept. (A subsequent negative test for the presence of Coronavirus does not shorten this 28-day deferral.)</del></p> <p>b) If the donor had <b>Coronavirus</b> symptoms of <b>COVID-19</b> and the donor had a negative PCR test for SARS-COV-2 (Coronavirus) infection, and</p> <ul style="list-style-type: none"> <li>• no further testing is required, and</li> <li>• any period of isolation has finished, and</li> <li>• all symptoms have resolved,</li> </ul> <p>accept</p> <p>If the donor had symptoms of <b>COVID-19</b> and the donor had a negative LFT for SARS-COV-2 and</p> <ul style="list-style-type: none"> <li>• no PCR test was taken, and</li> <li>• any period of isolation has finished, and</li> <li>• no further testing is required, and</li> <li>• it is at least seven days from the resolution of symptoms,</li> </ul> <p>accept <del>but tested negative for the presence of Coronavirus and it is at least 14 days from resolution of symptoms, accept.</del></p> <p>c) If the donor had <b>Coronavirus</b> symptoms of <b>COVID-19</b> and</p> <ul style="list-style-type: none"> <li>• the donor has not been tested for the presence of <b>SARS-COV-2 (Coronavirus) Coronavirus</b>, or</li> <li>• the donor had a test <del>has been tested</del> but is not aware of the result,</li> </ul> <p>When it is as least <del>seven</del> <b>28</b> days from the resolution of symptoms, accept</p> <p>d) If the donor tested positive for the presence of <b>SARS-COV-2 (Coronavirus)</b> but has not had symptoms of <b>COVID-19</b> and <b>Coronavirus infection</b>, <del>and it is at least 28 days from the date of their last positive test, accept. (A subsequent negative test for the presence of Coronavirus does not shorten this 28-day deferral.)</del></p> <ul style="list-style-type: none"> <li>• any period of isolation is finished, and</li> <li>• no further testing is required, and</li> <li>• the donor remains well, and</li> <li>• it is at least ten days since the last positive test was taken,</li> </ul> <p>accept</p>
<b>2. Person who has been in contact with <b>COVID-19 Coronavirus infection</b></b>	

<i>Includes:</i>	Donors who have been in contact with a confirmed or suspected case of <b>COVID-19 Coronavirus infection</b> .
<i>Excludes:</i>	Donors with symptoms of <b>COVID-19 Coronavirus infection</b> (see above). Donors who have had a positive test for the presence of SARS-CoV-2 (see above) Donors who have been in contact with individuals who are contacts of confirmed or suspected COVID-19.
<i>Obligatory:</i>	Must not donate if: Less than <del>14</del> <b>ten</b> days from the <del>first</del> <b>last</b> day of <del>contact</del> <b>isolation</b> . <del>If this</del>
<i>Discretionary</i> :	a) If it is at least <del>14</del> <b>ten</b> days since the <del>last</del> <b>day</b> of <del>contact</del> <b>isolation</b> and the donor remains well, accept.  b) If the donor has been advised: <del>that isolation is no longer required and the donor remains well, accept.</del> <ul style="list-style-type: none"> <li>• that any isolation period is now complete, or that isolation is not required, and</li> <li>• post-contact testing is complete, and the results are negative, and</li> <li>• no further testing is required, and</li> <li>• the donor remains well and they agree to report any post donation illness,</li> </ul> accept  <del>If the donor has not been required to isolate and they remain well and they agree to report any post donation illness, accept.</del>
<i>Additional Information:</i>	For donors who have had household contact with a case of COVID-19, the last day of contact is defined as: <ul style="list-style-type: none"> <li>• the last day that the contact had symptoms of COVID-19, or</li> <li>• If the contact did not have symptoms of COVID-19, the date of the contact's last positive test for SARS-CoV-2</li> </ul>
<b>3. Person requiring, isolation, <del>or</del> quarantine or testing after travel</b>	
<i>Includes:</i>	Donors required to isolate, <del>or</del> quarantine or <b>undertake testing</b> after travel. Donors who have returned from a quarantine country but are exempt from quarantine due to their job.
<i>Excludes:</i>	Donors with symptoms of <b>COVID-19 Coronavirus infection</b> (see above) Donors who have had a positive test for the presence of SARS-CoV-2 (see above)
<i>Obligatory:</i>	<del>Must not donate if a) Less than 10 days from the first day of isolation or quarantine.</del>  <del>b) Less than 10 days from the date of return to the UK for a donor who is exempt from quarantine for job purposes.</del> a) Must not donate if: <ul style="list-style-type: none"> <li>• any testing after travel has not been completed, or</li> <li>• the results of testing are not negative, or</li> <li>• the results of testing are not known</li> </ul> b) Must not donate while the donor is required to isolate or quarantine after arriving in the UK

<p><i>Discretionary</i> :</p>	<p><del>If it is at least 10 days since the first day of isolation or quarantine and the donor remains well, accept.</del> If the donor has been advised:</p> <ul style="list-style-type: none"> <li>• that a period of isolation or quarantine is not required, or that any quarantine or isolation period is complete, and</li> <li>• any testing following travel is negative and no further testing is required, and</li> <li>• the donor remains well,</li> </ul> <p>accept.</p>
<p><del>4. Donors of COVID-19 convalescent plasma</del> <b>4. Person having routine surveillance testing for SARS-COV-2 (Coronavirus) infection.</b></p>	
<p><i>Excludes</i></p>	<p>Donors requiring testing because of symptoms, contact or travel (see sections 1, 2 and 3 above).</p>
<p><del><i>Obligatory</i></del></p>	<p><del>Must not donate if less than 28 days since resolution of symptoms</del></p>
<p><i>Discretionary</i></p>	<p><del>If at least 28 days since resolution of symptoms, accept.</del></p> <p>Donors who have regular testing for the presence of SARS-COV-2 (Coronavirus) can be accepted to donate provided they have not had a positive test for the SARS-CoV-2 or symptoms of COVID-19 in the last ten days.</p> <p>This includes donors who work in a Health, Social Care or Educational setting.</p>
<p><b>5. Coronavirus SARS-COV-2 (Coronavirus) Vaccination</b></p>	
<p><i>Obligatory:</i></p>	<p><del>a) Recipients of a COVID-19 vaccine in the UK vaccination programme</del></p> <p>Must not donate if: Less than <b>48 hours</b> <del>seven days</del> after the most recent immunisation was given.</p> <p><del>b) Recipients of a COVID-19 vaccine outside the UK vaccination programme, including participants in clinical trials</del></p> <p><del>Must not donate if:</del></p> <ul style="list-style-type: none"> <li>• <del>Less than four weeks after the most recent immunization was given, or</del></li> </ul> <p><del>Refer to a Designated Clinical Support Officer if unsure.</del></p>
<p><i>Discretionary</i> :</p>	<p>a) If it is at least 48 hours have passed since <del>seven days after</del> the most recent <del>immunization</del> immunisation was given, and</p> <ul style="list-style-type: none"> <li>• the donor is well, with no ongoing local or systemic reaction to the vaccine, accept</li> </ul> <p>b) If the vaccine was given as part of an approved clinical trial and</p> <ul style="list-style-type: none"> <li>• more than 48 hours have passed since the most recent immunisation was given, and</li> </ul>

	<ul style="list-style-type: none"> <li>• the donor is well, with no ongoing local or systemic reaction to the vaccine, and</li> <li>• any deferral period specified in the study protocol has passed, accept</li> </ul>
<i>See if Relevant:</i>	<p>Clinical Trials <del>Transfusion</del> Immunisation – Non-live Infection - Acute</p>
<i>Additional Information:</i>	<p>Common coronaviruses cause colds and respiratory tract infections but are not considered a risk for transfusion recipients. Since 2002 there have been outbreaks in humans of new strains of coronavirus, associated with severe pulmonary infections and mortality rates of 10-35% e.g. SARS and MERS.</p> <p>COVID-19 is an illness caused by infection with a newly identified Coronavirus, SARS-CoV-2.</p> <p>Some individuals will have symptoms for a protracted length of time after the systemic and respiratory symptoms of the acute infection have resolved. A wide range of symptoms, including cardiac and neurological, have been reported. Donors may not realise the importance of declaring some symptoms. It is important to identify any of the specific ongoing symptoms such as chest pain, palpitations, shortness of breath, fatigue, even if seemingly mild or infrequent, that suggest that a donor may not have fully recovered to their pre-COVID-19 state of health, and that may put a donor at risk of an adverse event.</p> <p>This entry has been revised several times during the COVID-19 pandemic in response to evolving evidence and changes in public health and government advice. The list of COVID19 symptoms in this entry is taken from UK Health Security Agency (fever, cough and loss of taste/smell). Not all individuals with confirmed SARS-CoV-2 infection report these symptoms. But if the donor has recovered from symptoms of a cold or upper respiratory tract infection (URTI) and has had a negative PCR test for SARS-CoV-2, it seems likely they had a common cold or URTI. The acute infection entry within this DSG has provision to accept donors who have recovered from a simple cold or URTI within two weeks of recovery. This is supported by the lack of evidence that respiratory viruses are transmitted by transfusion. The different deferral periods after negative PCR and LFT tests reflect the different sensitivities of these methods.</p> <p>The obligatory deferral period after contact with COVID-19 has been set as 10 days; this is approximately twice the median incubation period of SARS-CoV-2 (five to six days) and is consistent with other entries in the DSG.</p> <p>The guidance within this entry is focussed on COVID-19. Donors who report MERS or SARS, or contact with these infections, should be referred to a DCSO.</p> <p><del>Donors who are known to have antibodies to Coronavirus are eligible to donate provided they have not had symptoms of Coronavirus Infection in the last 28 days.</del></p> <p><del>Donors who have had screening for the presence of Coronavirus for reasons other than suspected infection or contact (e.g. occupational) can be accepted to donate provided they have not had a positive test for the virus or symptoms of Coronavirus in the last 28 days.</del></p>

	<p><del>Donors who have travelled may be required to self-isolate (also termed quarantine) on their entry into the UK. This will depend on country or area of a country travelled from, and when the entry into the UK occurred. Donors will be aware of the UK border rules at the time of their travel. Some donors may be exempt from self-isolation due to the jobs they do; this exemption does not apply to donating blood.</del></p> <p>Individuals vaccinated with inactivated viruses or vaccines that do not contain live agents can usually be accepted without any deferral. COVID-19 vaccines currently licensed in the UK, including the AstraZeneca, Moderna and Pfizer/BioNTech COVID-19 vaccines, are non-live and as such do not pose a transfusion safety risk. Nevertheless, as these are new vaccines, a <b>seven-day 48-hour</b> deferral after <b>immunisation immunization</b> is recommended to ensure donor and donation safety. This will also reduce the risk of a donation being discarded if a vaccine recipient develops symptoms directly related to the vaccine <b>in-the-week</b> after donation.</p> <p>Several other coronavirus vaccines are currently under review by regulatory authorities in the UK and elsewhere. Donor selection guidelines will be reviewed <b>if-and</b> when any new COVID-19 vaccine is approved for use in the UK.</p>
<p><i>Post Donation Information:</i></p>	<p>There is no evidence at present that coronaviruses can be transmitted by blood transfusion and therefore these measures are precautionary.</p> <p>Donors must be provided with information about contacting the blood service if they develop any illness after blood or component donation.</p> <p>Donors may inform the blood service that they have received advice since donation to isolate due to contact prior to donation. They may have been advised to have a test for Coronavirus.</p> <p>It is only necessary to recall the donations from donors who:</p> <ul style="list-style-type: none"> <li>• report symptoms of <b>COVID-19 Coronavirus infection</b> starting within 48 hours of <b>on-or-before the fifth day after</b> donation, and/or</li> <li>• have tested positive for the presence of <b>SARS-COV-2 (Coronavirus) Coronavirus on or before the fifth day after donation.</b> when the sample was taken within 48 hours of donation</li> </ul>
<p><i>Information:</i></p>	<p><del>This is a requirement of the Blood Safety and Quality Regulations 2005.</del></p>
<p><i>Reason for change:</i></p>	<p><del>The obligatory deferral for donors required to quarantine after travel has been reduced from 14 days to 10 days, in line with current UK government quarantine requirements.</del> Extensive revision of entry. The deferral after confirmed infection, contact and vaccination have been reduced. Clarifications that testing after infection, contact and travel must be complete before the donor is accepted, have been added. Specific guidance on household contacts has been added. The time period for post donation recall has been reduced. Reference to convalescent plasma donation has been removed.</p>

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## 38.2 Transfusion

<i>Obligatory:</i>	<p><b>1. Must not donate if:</b> At any time the donor has:</p> <p>a) Received, or thinks they may have received, a transfusion of blood or blood components, in a country endemic for malaria or South American trypanosomiasis.</p> <p>b) Received treatment with blood derived coagulation factor concentrates. This includes prothrombin complex to reverse over-anticoagulation.</p> <p><b>2. Must not donate if:</b> Since January 1st 1980:</p> <p>a) Anywhere in the world the donor has received, or thinks they may have received, a transfusion with red cells, platelets, fresh frozen plasma (FFP), cryoprecipitate, cryodepleted plasma, <b>convalescent plasma</b>, granulocytes, buffy coat preparations, intravenous or subcutaneous human normal immunoglobulin. This includes mothers whose babies have required intra-uterine transfusion.</p> <p>b) Has had a plasma exchange performed.</p>
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<i>Discretionary:</i>	<p>1. a) If on medical inquiry it is unlikely that the donor has been transfused accept.</p> <p>b) If treatment with human immunoglobulin has been limited to specific immunoglobulin given as prophylaxis (e.g. anti D, anti tetanus or hepatitis immunoglobulin etc.), accept.</p> <p>2. Autologous Transfusion in:</p> <ul style="list-style-type: none"> <li>• the United Kingdom</li> <li>• North America</li> <li>• Australasia</li> <li>• Western Europe (at any time)</li> <li>• EU member states (from February 2005)</li> </ul> <p>If only the donor's own blood has been used, accept.</p> <p>3. Donor transfused before 1st January 1980:</p> <p>a) If before 1st January 1980 the donor received, or thinks they may have received, a transfusion in a country endemic for malaria or South American trypanosomiasis, check the 'Geographical Disease Risk Index'. If transfused in an at risk country and a validated malarial antibody test and/or (as appropriate) a validated test for T.cruzi antibody is negative, accept.</p> <p>b) If the transfusion was not within a risk area for either malaria or South American trypanosomiasis, accept.</p> <p><del>4. Donor transfused with COVID-19 convalescent plasma:</del></p> <p><del>a) If the donor was only transfused with COVID-19 convalescent plasma and,</del></p> <ul style="list-style-type: none"> <li><del>• the transfusion took place in the UK,</del></li> <li><del>• no other blood components were administered, and</del></li> <li><del>• it is two or more months since the transfusion took place,</del></li> </ul> <p><del>accept for COVID-19 convalescent plasma donation only.</del></p>
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	<p>-</p> <p><del>b) If the donor was only transfused with COVID-19 convalescent plasma outside UK, and they meet all other criteria listed in 4a: Refer to a DCSO for review of transfusion history and consideration of other risks, including malaria and T. cruzi.</del></p>
See if Relevant:	<p>Bleeding Disorder <del>Coronavirus Infection</del> Immunoglobulin Therapy Immunosuppression Malaria Prion Associated Diseases South American Trypanosomiasis Geographical Disease Risk Index</p>
Additional Information:	<p>Transfused donors have previously contributed to the spread of some diseases. This happened with hepatitis C.</p> <p>Transfusions in some countries may have put the donor at risk of malaria or South American trypanosomiasis. It is necessary to exclude these infections before accepting the donor.</p>

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	<p><b>Coagulation concentrates:</b> People who have received blood derived coagulation concentrates (these are made from the blood of many donors) may have been put at risk of infections that can be passed through blood.</p> <p><b>Donors transfused since 1980:</b> In the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then there have been several cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD.</p> <p>In view of this, people transfused, or possibly transfused, since 1980 are now excluded from donation. This date is before BSE, which is believed to have caused vCJD, was prevalent.</p> <p>Plasma exchange results in a patient being exposed to multiple donors. In view of the increased vCJD risk, donations may not be taken from individuals who have had a plasma exchange performed since 1980.</p> <p><b>COVID-19 convalescent plasma</b> <del>As part of the response to the COVID-19 pandemic, UK transfusion services have collected convalescent plasma (CP) from individuals who have recovered from this infection. In line with a recommendation from SaBTO, recipients of COVID-19 CP can be accepted two months after transfusion and do not need to wait for four months as detailed in the Blood Safety and Quality Regulations (BSQR). This change has been implemented to ensure the ongoing supply of CP should its use become more widespread.</del></p> <p><del>Individuals who receive CP outside the UK must be referred to a DCSO for detailed assessment of their transfusion and travel history. For donors with potential exposure to malaria or T. cruzi, expert advice may be required regarding discretionary testing to optimise the timing of donation for COVID-19 antibodies.</del></p>
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Reason for change:	<p><del>A discretion has been added to allow recipients of COVID-19 convalescent plasma to donate convalescent plasma on their recovery. The guidance for autologous transfusion in Europe has been clarified.</del></p> <p>The discretion which allowed recipients of COVID-19 convalescent plasma to donate convalescent plasma on their recovery from COVID-19 has been removed.</p>
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## 38.3 Clinical Trials

### 2. Covid-19 Clinical Trials

Discretionary:	<p>For donors who have been enrolled in Covid-19 treatment trials, if:</p> <ul style="list-style-type: none"> <li>the donor is fully recovered from Covid-19 for 28 days or more, and</li> <li>the treatment which the donor received (or was randomised to) in the trial does not prevent donation, and</li> <li>the donor meets all other criteria in the Donor Selection Guidelines, accept.</li> </ul>
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<p>The table shows individual treatments used in Covid-19 clinical trials and their consequences for whole blood or component donation. Donors must be assessed on the basis of their recovery from Covid-19 as well as the information below. If in doubt, refer to a DCSO.</p>	
Treatment Received	Consequence for donation
Short course of steroids e.g. dexamethasone	Can donate, provided at least 7 days from last date of treatment
Antivirals e.g. lopinavir, remdesivir, ritonavir	Can donate, provided at least 7 days from last date of treatment
Convalescent plasma	<p><del>Can donate convalescent plasma only, provided at least 2 months from date of convalescent plasma transfusion</del></p> <p>Permanent Deferral (see Transfusion entry)</p>
Anti-SARS-CoV-2 monoclonal antibodies e.g. AZD7442, bamlanivimab, Regeneron	Defer for 12 months from last day of treatment
Monoclonal antibodies that affect the immune system e.g. infliximab, MEDI3506, ravulizumab, sarilumab, tocilizumab	Defer for 12 months from last day of treatment
Immunosuppressive or immunomodulatory therapy e.g. acalabrutinib, anakinra, baricitinib, bemcentinib, interferon- $\beta$ 1a, interferon $\beta$ 1b, recombinant IL-7 (CYT107), zilucoplan	Defer for 12 months from last day of treatment

Reason for change:	<b>Addition of specific information for Covid-19 clinical trials</b> Removal of the discretion allowing recipients of Covid-19 convalescent plasma to donate convalescent plasma after recovery.
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