



Therapeutic Goods (Standard for Faecal Microbiota Transplant Products) (TGO 105) Order 2020

I, John Skerritt, as delegate of the Minister for Health, make the following order.

Dated 6 August 2020

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

Contents

Part 1—Preliminary	1
1 Name.....	1
2 Commencement	1
3 Authority.....	1
4 Definitions	1
5 Standard.....	3
6 Application	3
Part 2—Requirements for FMT products	3
Division 1—General requirements	3
7 What this Division is about.....	3
8 General requirements	4
Division 2—Requirements relating to screening	4
9 What this Division is about.....	4
10 Proposed donors and accepted donors	4
11 General screening procedures	5
12 Medical and social history	5
13 Blood, stool and other samples—taking	7
14 Blood, stool and other samples—testing.....	8
15 Physical assessment	11
Division 3—Requirements following collection	12
16 What this Division is about.....	12
17 Microbial control procedures	12
Schedule 1—Ineligibility criteria for donor selection	14

Part 1—Preliminary

1 Name

- (1) This instrument is the *Therapeutic Goods (Standard for Faecal Microbiota Transplant Products) (TGO 105) Order 2020*.
- (2) This instrument may also be cited as TGO 105.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date / Details
1. The whole of this instrument	1 July 2021.	1 July 2021

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 10 of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) biological;
- (b) container;
- (c) health practitioner;
- (d) manufacture;
- (e) medicine;
- (f) Register;
- (g) standard;
- (h) supply; and
- (i) therapeutic goods.

In this instrument:

accepted donor has the meaning given by subsection 10(2).

Act means the *Therapeutic Goods Act 1989*.

allogeneic use, in relation to an FMT product, means administration to, or application in the treatment of, a person other than the person from whom the stool used in the manufacture of the FMT product was collected.

autologous use, in relation to an FMT product, means administration to, or application in the treatment of, the person from whom the stool used in the manufacture of the FMT product was collected.

blood means whole blood collected from a single human donor and that is:

- (a) used for infectious disease testing; or
- (b) processed either for transfusion or further manufacturing.

blood components means any of the following therapeutic components of blood that can be prepared by centrifugation, filtration or freezing using conventional methodologies in blood establishment:

- (a) haematopoietic progenitor cells;
- (b) plasma;
- (c) platelets;
- (d) red cells;
- (e) white cells.

collection period, in relation to an accepted donor, means a period of 90 days or less over the course of which stool is collected from the accepted donor for use in the manufacture of FMT products, other than fresh FMT products.

critical materials means all the materials used in the collection of stool or the manufacture of FMT products that may directly affect the quality, safety or efficacy of the FMT products.

faecal microbiota transplant product has the same meaning as in the Regulations.

FMT products means therapeutic goods that are faecal microbiota transplant products.

fresh FMT products means FMT products that are:

- (a) manufactured using stool that is processed in accordance with subsection 17(3); and
- (b) administered to, or applied in the treatment of, a person in accordance with subsection 17(4).

haematopoietic progenitor cells means primitive pluripotent haematopoietic cells capable of self-renewal as well as maturation into any of the haematopoietic lineages, including committed and lineage-restricted progenitor cells.

HBsAg means hepatitis B surface antigen.

HAV means hepatitis A virus.

HBV means hepatitis B virus.

HCV means hepatitis C virus.

HIV-1 means human immunodeficiency virus type 1.

HIV-2 means human immunodeficiency virus type 2.

HTLV-1 means human T-lymphotropic virus type 1.

HTLV-2 means human T-lymphotropic virus type 2.

in-house IVD medical device has the same meaning as in the MD Regulations.

IVD medical device has the same meaning as in the MD Regulations.

MD Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

proposed donor has the meaning given by subsection 10(1).

Regulations means the *Therapeutic Goods Regulations 1990*.

Therapeutic Goods Administration has the same meaning as in the Regulations.

TGO 88 means the *Therapeutic Goods Order No.88 Standards for donor selection, testing, and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products*.

Note: TGO 88 is a legislative instrument and is published on the Federal Register of Legislation at www.legislation.gov.au.

5 Standard

The matters specified in this instrument constitute a standard for FMT products.

6 Application

This instrument applies to FMT products.

Note 1: FMT products are biologicals.

Note 2: Therapeutic goods containing one or more strains of microorganisms, known to be present in stool, that are characterised and grown from established isolates with standardised consistency are medicines and not FMT products.

Part 2—Requirements for FMT products

Division 1—General requirements

7 What this Division is about

This Division specifies the general requirements that must be met in the manufacture of FMT products.

8 General requirements

- (1) FMT products must only be manufactured using stool that has been collected from an accepted donor.
- (2) The procedures and controls used in the manufacture of FMT products must:
 - (a) be clearly defined and documented in a systematic way in the form of written policies and standard operating procedures; and
 - (b) ensure that the FMT products are safe for use; and
 - (c) ensure the FMT products are manufactured consistently and comply with the specifications for the products; and
 - (d) be systematically reviewed and, if appropriate, modified.
- (3) The procedures must ensure the traceability of stool used in the manufacture of FMT products from the collection of the stool to the supply of the products.
- (4) The critical materials used in the manufacture of FMT products must not adversely affect the quality or safety of the products.
- (5) The personnel involved in the manufacture of FMT products must be appropriately qualified and competent to manufacture FMT products.
- (6) The test methods used in the manufacture of FMT products must be validated or verified.
- (7) The equipment and reagents used in the manufacture of FMT products must be qualified.
- (8) A system must be established and maintained to:
 - (a) handle complaints made or concerns raised by any person in relation to the manufacture of FMT products; and
 - (b) ensure process and quality improvement functions and activities are carried out regularly.

Division 2—Requirements relating to screening

9 What this Division is about

This Division specifies procedures relating to screening that must be implemented in the manufacture of FMT products.

10 Proposed donors and accepted donors

- (1) A ***proposed donor*** is a person, other than an accepted donor, from whom stool is proposed to be collected for use in the manufacture of FMT products.
- (2) An ***accepted donor*** is a person:
 - (a) who has undertaken the screening procedures applicable to proposed donors specified in this Division; and

-
- (b) following those procedures, has been determined to be eligible to donate stool for use in the manufacture of FMT products in accordance with this Division;
but does not include a person mentioned in subsection (3).
 - (3) A person ceases to be an ***accepted donor*** if the person fails to satisfy any of the screening procedures applicable to accepted donors specified in this Division.

11 General screening procedures

- (1) Screening procedures must be implemented in relation to proposed donors and accepted donors to ensure that the quality, safety and efficacy of FMT products is acceptable.
- (2) The screening procedures must include:
 - (a) review of medical and social history in accordance with section 12; and
 - (b) taking of blood, stool or other samples in accordance with section 13; and
 - (c) testing of blood, stool or other samples in accordance with section 14; and
 - (d) physical assessment in accordance with section 15.

12 Medical and social history

Medical and social history of proposed donors

- (1) A complete medical and social history, covering the ineligibility criteria for donor selection specified in Schedule 1 and any other relevant matters, must be obtained from a proposed donor by interview, and reviewed for the purposes of screening.
- (2) The interview must be:
 - (a) conducted by an interviewer who is appropriately qualified; and
 - (b) undertaken not more than 30 days prior to the first collection of stool for use in the manufacture of FMT products; and
 - (c) held face to face between the proposed donor and the interviewer, to the extent that it is possible in the circumstances; and
 - (d) documented.

Medical and social history of accepted donors

- (3) The complete medical and social history must be repeated in relation to an accepted donor on an ongoing basis, such that each complete medical and social history is obtained within 90 days of the last complete medical and social history.
- (4) An abridged medical and social history must be obtained, reviewed and documented, each time stool is collected for use in the manufacture of FMT products from an accepted donor, covering any relevant matters determined on the basis of a risk assessment, including one or more of the ineligibility criteria for donor selection specified in Schedule 1.

Review of an accepted donor

- (5) Where the circumstances of an accepted donor change in relation to either the ineligibility criteria for donor selection specified in Schedule 1 or a disease or condition referred to in subsection (8), the relevant aspects of the medical and social history of the donor must be reviewed with respect to those changes before:
- (a) stool collected from the accepted donor is used in the manufacture of FMT products; and
 - (b) FMT products that are manufactured using stool collected from the accepted donor are released for supply.

Screening requirements for allogeneic use

- (6) Where a proposed donor or accepted donor meets any of the ineligibility criteria for donor selection specified in column 2 of an item in the table in Schedule 1, the donor is subject to the period of ineligibility specified in column 3 of that item in relation to the collection of stool from that donor for use in the manufacture of FMT products intended for allogeneic use.

Screening requirements for autologous use

- (7) Where a proposed donor or accepted donor meets any of the ineligibility criteria for donor selection specified in column 2 of an item in the table in Schedule 1, a risk assessment must be conducted as to whether the donor should be subject to the period of ineligibility specified in column 3 of that item, in relation to the collection of stool from that donor for use in the manufacture of FMT products intended for autologous use.

Diseases or conditions not mentioned in Schedule 1

- (8) Where a proposed donor or accepted donor has a disease or condition that may compromise the quality, safety or efficacy of FMT products manufactured using stool collected from the donor, and the disease or condition is not mentioned in the table in Schedule 1, then stool collected from that donor must not be used in the manufacture of FMT products, unless:
- (a) criteria for donor selection and periods of ineligibility are applied that support and justify the quality, safety and efficacy of the FMT products for the intended use of the products, and the application of the criteria is documented; or
 - (b) a registered medical practitioner has agreed to, and documented the rationale for, the use of the stool in the manufacture of FMT products.

Stool collected outside Australia

- (9) Where stool is proposed to be collected outside Australia, a risk assessment must be conducted as to whether any additional matters, including additional medical and social history criteria and periods of ineligibility, need to be considered and documented in addition to the ineligibility criteria specified in Schedule 1.

Upper and lower age limits

- (10) Upper and lower age limits must be applied in relation to a proposed donor, having regard to the intended use of the FMT products and the extent to which the age of the proposed donor may compromise the quality, safety, or efficacy of FMT products that are manufactured using stool collected from that donor.

13 Blood, stool and other samples—taking

Fresh FMT products

- (1) Where stool is to be collected from a person for use in the manufacture of fresh FMT products, blood samples must be taken:
- (a) from the person (as a proposed donor) not more than 30 days before the first collection of stool; and
 - (b) from the person (as an accepted donor) at the time of the first collection of stool; and
 - (c) from the person (as an accepted donor) on an ongoing basis, such that each blood sample is taken within 90 days of the last blood sample.
- (2) Where stool is to be collected from a person for use in the manufacture of fresh FMT products, stool samples must be taken:
- (a) from the person (as a proposed donor) not more than 30 days before the first collection of stool; and
 - (b) from the person (as an accepted donor) at the time of the first collection of stool; and
 - (c) from the person (as an accepted donor) at regular intervals determined on the basis of a risk assessment.

FMT products other than fresh FMT products

- (3) Where stool is to be collected from a person for use in the manufacture of FMT products, other than fresh FMT products, blood samples must be taken in accordance with either of the following paragraphs:
- (a) blood samples must be taken:
 - (i) from the person (as a proposed donor) not more than 30 days before the first collection of stool; and
 - (ii) from the person (as an accepted donor) on the day that, or not more than 30 days after, the collection period ends; and
 - (iii) from the person (as an accepted donor) on an ongoing basis, such that each blood sample is taken within 90 days of the last blood sample; or
 - (b) blood samples must be taken:
 - (i) from the person (as a proposed donor) not more than 30 days before the first collection of stool; and
 - (ii) from the person (as an accepted donor) not less than 90 days after the blood samples were collected in accordance with subparagraph (i); and

-
- (iii) from the person (as an accepted donor) on an ongoing basis, such that each blood sample is taken within 90 days of the last blood sample.
- (4) Where stool is to be collected from a person for use in the manufacture of FMT products, other than fresh FMT products, stool samples must be taken:
- (a) from the person (as a proposed donor) not more than 30 days before the first collection of stool; and
 - (b) from the person (as an accepted donor) on the day that, or not more than 30 days after, the collection period ends; and
 - (c) from the person (as an accepted donor) on an ongoing basis, such that each stool sample is taken within 90 days of the last stool sample.

Other samples

- (5) In addition to the samples required to be taken in accordance with this section, samples other than blood or stool samples may be taken from a proposed donor or an accepted donor where scientifically justified in the circumstances.

Stool samples for storage

- (6) A stool sample must be taken from each stool that is collected for use in the manufacture of FMT products, and stored in accordance with subsections 14(16) and 14(17).

Note: Stool samples are taken under this subsection for the purposes of storage and do not need to be tested in accordance with section 14.

14 Blood, stool and other samples—testing

General testing requirements

- (1) Samples taken in accordance with section 13, other than stool samples taken in accordance with subsection 13(6), must be tested as soon as practicable after collection in accordance with this section, and within the claimed sample stability timeframe specified by the manufacturer of the IVD medical device or in-house IVD medical device to be used for the testing.
- (2) Samples that are tested for infectious diseases must be tested using IVD medical devices or in-house IVD medical devices that:
- (a) use the most appropriate methodology available for testing the samples in relation to the target organisms; and
 - (b) where testing is conducted in Australia—are either included in the Register or exempt from the requirement to be included in the Register, or the subject of an approval or authority under the Act; and
 - (c) where testing is conducted outside Australia:
 - (i) are approved by a relevant regulatory authority in the country in which the testing is conducted; and
 - (ii) are used in a facility that has been approved for such testing by a relevant regulatory authority in the country in which the testing is conducted; and

(iii) are considered acceptable by the Therapeutic Goods Administration.

- (3) Where testing is conducted by a laboratory that is not under the direct control of the manufacturer of the FMT products:
- (a) the testing must be conducted under a contract between the manufacturer and the laboratory; and
 - (b) the contract mentioned in paragraph (a) must clearly set out the responsibilities of the manufacturer and the laboratory, and include arrangements to ensure information relating to matters in this section and any other relevant details relating to the IVD medical devices or in-house IVD medical devices used for such testing can be obtained from the laboratory.

Blood sample testing

- (4) The following tests must be conducted in relation to blood samples taken in accordance with subsection 13(1) or paragraph 13(3)(a):
- (a) C-reactive protein (CRP), full blood count (FBC) and liver function tests (LFTs); and
 - (b) serology testing for antibodies to HIV-1 / HIV-2, HBV, HCV, HTLV-1 / HTLV-2, *Strongyloides stercoralis*, and syphilis (*Treponema pallidum*); and
 - (c) HAV testing (unless RNA testing is conducted on the stool samples); and
 - (d) nucleic acid amplification testing for HIV-1, HBV and HCV.
- (5) The following tests must be conducted in relation to the blood samples taken in accordance with subsection 13(3)(b):
- (a) C-reactive protein (CRP), full blood count (FBC) and liver function tests (LFTs); and
 - (b) serology testing for antibodies to HIV-1 / HIV-2, HBV, HCV, HTLV-1 / HTLV-2, *Strongyloides stercoralis*, and syphilis (*Treponema pallidum*); and
 - (c) HAV testing (unless RNA testing is conducted on the stool samples).

Stool sample testing

- (6) Subject to subsections (7) and (8), stool samples must be tested for each of the following microorganisms:
- (a) *Campylobacter* spp.;
 - (b) *Cryptosporidium* spp.;
 - (c) *Entamoeba histolytica*;
 - (d) *Giardia*;
 - (e) *Helicobacter pylori*, where stool is proposed to be collected for use in the manufacture of FMT products delivered by the upper gastrointestinal route;
 - (f) multidrug-resistant organisms (MDROs) including:
 - (i) extended spectrum beta-lactamase (ESBL)-producing Enterobacterales;
 - (ii) vancomycin-resistant enterococci (VRE);

-
- (iii) carbapenemase-producing Enterobacterales (CPE);
 - (iv) methicillin-resistant *Staphylococcus aureus*;
 - (g) norovirus;
 - (h) rotavirus;
 - (i) *Salmonella* spp.;
 - (j) *Shigella* spp.;
 - (k) toxigenic *Clostridioides difficile*;
 - (l) any other microorganism of clinical significance that may affect the quality or safety of the stool collected for use in the manufacture of FMT products, determined on the basis of a risk assessment.

- (7) Stool samples taken in accordance with paragraph 13(2)(c) must be tested for the microorganisms mentioned in subsection (6) determined on the basis of a risk assessment, such that every microorganism is tested at least once every 90 days.

Other sample testing

- (8) The microorganisms mentioned in subsection (6) may be tested using a sample taken in accordance with subsection 13(5), where the test method is scientifically justified in the circumstances.

Additional testing requirements

- (9) Where stool is to be collected outside Australia, a risk assessment must be conducted and documented in relation to whether additional blood, stool or other samples may be needed to be tested to ensure the quality, safety and efficacy of the FMT products.
- (10) Where FMT products are intended to be administered to, or applied in the treatment of, patients with increased susceptibility to infection, further testing of blood, stool and other samples must be considered in order to ensure patient safety.

Assessment of results

- (11) Where FMT products are intended for autologous use, and the testing of blood, stool or other samples in accordance with this section has resulted in repeatedly reactive results:
 - (a) the FMT products and stool collected for use in the manufacture of those products must be segregated and quarantined from any other stool or FMT products; and
 - (b) the justification for the autologous use must be documented and maintained.
- (12) Where the FMT products are intended for allogeneic use, and the testing of blood, stool or other samples in accordance with this section, other than testing of blood samples in accordance with paragraphs (4)(a) and (5)(a), has resulted in a reactive result, then the stool collected for use in the manufacture of FMT products must not be used in such manufacture or, if FMT products are

manufactured from the stool, the products must not be released for supply, unless:

- (a) confirmatory testing of an initial reactive result in relation to such samples confirms that the result was a biological false reactive; or
 - (b) further testing of samples indicates that the presence of the specified microorganism has cleared.
- (13) Where abnormal results are obtained from testing conducted in accordance with paragraphs (4)(a) or (5)(a), a medical practitioner must assess the potential impact on the quality, safety or efficacy of stool collected, or to be collected, for use in the manufacture of FMT products intended for allogeneic use.

Notification and record-keeping

- (14) Procedures must be implemented for notifying the proposed donor, the accepted donor, health practitioners, hospitals and other health facilities, about a test result that is indicative of a disease or carrier state at the time of the collection of the sample.
- (15) Records must be maintained in relation to the following:
- (a) the IVD medical device or in-house IVD medical device used for infectious disease testing;
 - (b) any test modifications;
 - (c) the results of analytical and clinical performance testing;
 - (d) any evaluation of, and anomalies in, the test results.

Storage of blood and stool samples

- (16) Blood and stool samples collected from an accepted donor (including any serum or plasma) must be placed in long-term storage in accordance with the following conditions:
- (a) blood samples must be stored at or below minus 20°C; and
 - (b) stool samples must be stored at or below minus 70°C; and
 - (c) retained for a minimum of two years after the expiry date of the products.
- (17) Despite paragraphs 14(16)(a) and (b), other storage specifications may be used in relation to the samples, if those specifications are validated (including in relation to temperature) or recommended by the manufacturer of the IVD medical device or in-house IVD medical device used to test the samples.

15 Physical assessment

- (1) A physical assessment must be conducted in relation to a proposed donor not more than 30 days before the first collection of stool for use in the manufacture of FMT products.
- (2) Subsequent physical assessments must be conducted in relation to an accepted donor on an ongoing basis, such that each physical assessment is conducted within 90 days of the last physical assessment.

-
- (3) A physical assessment must:
 - (a) include a clinical assessment of any physical features or characteristics that may indicate that a proposed donor or accepted donor is at risk of a communicable disease potentially transmissible by faecal microbiota transplant; and
 - (b) be conducted by an appropriate health practitioner.
 - (4) Where a physical assessment identifies an unacceptable risk of communicable disease transmission in relation to a proposed donor or accepted donor, the donor is ineligible to donate stool for use in the manufacture of FMT products until a subsequent physical assessment is conducted that does not identify the risk.

Division 3—Requirements following collection

16 What this Division is about

This Division specifies procedures relating to microbial control that must be implemented in the manufacture of FMT products.

17 Microbial control procedures

General requirements

- (1) Microbial control procedures that are validated must be implemented in the manufacture of FMT products and must:
 - (a) include a strategy to minimise the proliferation of intrinsic microbial contamination and to prevent extrinsic microbial contamination of stool during the manufacture of FMT products; and
 - (b) specify storage, handling and transportation requirements (including in relation to temperature and duration) for stool used in the manufacture of FMT products.

Immediate processing of stool following collection

- (2) Stool used in the manufacture of FMT products, other than fresh FMT products, must:
 - (a) be processed as soon as possible, and not later than 6 hours after defaecation; and
 - (b) during any interval to the processing mentioned in paragraph (a) including transportation of the stool—be cooled to 4°C or kept as otherwise validated by the manufacturer; and
 - (c) following the processing mentioned in paragraph (a)—be stored in accordance with subsection (5).

Processing and storage of stool used in the manufacture of fresh FMT products

- (3) Stool collected from an accepted donor for use in the manufacture of fresh FMT products must be processed not later than 6 hours after defaecation:

-
- (a) at ambient temperature (maximum 37°C); or
 - (b) under specifications set and validated by the manufacturer.
- (4) Fresh FMT products must be administered to, or applied in the treatment of, a person:
- (a) on the same day the stool is collected; or
 - (b) not later than 5 days after the stool is collected where the fresh FMT products are stored under conditions that will not impact the quality, safety or efficacy of those products.

Storage and transportation of stool and FMT products

- (5) FMT products, other than fresh FMT products, and stool to be used in the manufacture of FMT products must be stored:
- (a) at or below minus 70°C in a suitable cryopreservation agent for not longer than 12 months; or
 - (b) in accordance with justified time and temperature specifications.
- (6) FMT products must be appropriately sealed within a sterile container that:
- (a) prevents leakage of the FMT products from the container; and
 - (b) ensures that any breach of integrity of the container is evident.
- (7) FMT products, other than fresh FMT products, must be transported in accordance with justified time and temperature specifications.

Schedule 1—Ineligibility criteria for donor selection

Note: See section 12.

Ineligibility criteria for donor selection		
Column 1	Column 2	Column 3
Item	Medical and social history criteria	Period of ineligibility
1	a person who is infected with: (a) HIV-1; (b) HIV-2; (c) HTLV-1; (d) HTLV-2; or (e) syphilis	permanently ineligible
2	a person who is infected with: (a) HAV; (b) HBV; or (c) HCV	ineligible until an uninfected state is established
3	a person who has been a recipient of viable, non-human animal cells or tissues	permanently ineligible
4	a person who is at risk of prion disease because the person has been, or potentially been, exposed to the putative causative agent of one of the family of pathogenic transmissible spongiform encephalopathies, including: (a) genetic (familial) exposure; (b) environmental exposure, including living in or visiting England, Scotland, Wales, Northern Ireland or the Isle of Man for a cumulative period of 6 months or more, at any time between 1 January 1980 and 31 December 1996; or (c) iatrogenic exposure, including receiving a transfusion or injection of blood or blood components while in England, Scotland, Wales, Northern Ireland or the Isle of Man at any time on or after 1 January 1980	permanently ineligible
5	a person who has received an injection of any substance in connection with a use that is not a therapeutic use or cosmetic use	ineligible for at least 5 years from the last injection
6	a person who has engaged in sexual activity that puts the person at an increased risk of acquiring infectious diseases that could be transmitted through stool	ineligible for at least 12 months from the last sexual contact
7	a person who has been exposed to any of the following risks of acquiring a blood borne infection transmissible by stool:	(a) where the person tests negative for HCV using nucleic acid amplification

Ineligibility criteria for donor selection		
Column 1	Column 2	Column 3
Item	Medical and social history criteria	Period of ineligibility
	(a) mucosal splash with blood or other bodily fluids; (b) needle stick injury; (c) tattoo; (d) body piercing (including earring); or (e) acupuncture or dry-needling, unless performed using sterile, single-use needles	testing—ineligible for at least 4 months from exposure; or (b) in all other circumstances—ineligible for at least 6 months from exposure
8	a person who has been a recipient of human pituitary-derived hormone	permanently ineligible
9	a person who has an active infection, fever or infectious illness	ineligible for at least 2 weeks from the date of full recovery
10	a person who has a history of functional gastrointestinal disorders	permanently ineligible
11	a person who has a history of gastrointestinal malignancy	permanently ineligible
12	a person who has a known genetic polyp condition	permanently ineligible
13	a person who has a history of major gastrointestinal surgery	permanently ineligible
14	a person using antibiotics or immunosuppressive agents	ineligible for at least 90 days from ceasing use
15	a person who has symptoms of a gastrointestinal illness including abdominal pain, diarrhoea, fever, nausea, vomiting, and haematochezia	ineligible for at least 30 days since last showing symptoms
16	a person who has had contact with a household member who has symptoms of a gastrointestinal illness including abdominal pain, diarrhoea, fever, nausea, vomiting, haematochezia	ineligible for at least 30 days since contact
17	a person who has a history of any autoimmune disease	permanently ineligible
18	a person who has a metabolic syndrome or diabetes	permanently ineligible
19	a person who has a body mass index of, or greater than, 30 kg per m ²	ineligible until that person has a body mass index less than 30 kg per m ²
20	a person who: (a) has travelled to a country or place in Australia with a high endemic risk of travellers' diarrhoea or multidrug-resistant organisms; or (b) has had exposure to similar epidemiological situations as described in paragraph (a)	(a) ineligible for a period of time based on a risk assessment using the most up-to-date epidemiological data; or (b) where epidemiological data is not available—ineligible for at least 90 days from

Ineligibility criteria for donor selection		
Column 1	Column 2	Column 3
Item	Medical and social history criteria	Period of ineligibility exposure
21	a person who is at risk of being a carrier of multidrug-resistant organisms, including a person who: <ul style="list-style-type: none"> (a) is or has been a healthcare worker with exposure to patients in hospitals or long-term care facilities; (b) has recently been hospitalised or discharged from long-term care facilities; (c) has regularly attended or regularly attends outpatient medical or surgical clinics; (d) has recently engaged in medical tourism 	ineligible until it has been demonstrated that the person is not a carrier of a multidrug-resistant organism
22	a person who has been vaccinated with a live vaccine, where there is a risk of transmission of the vaccine strain	ineligible for a period of time that is consistent with defined criteria for the vaccine
23	a person who has potentially been exposed to: <ul style="list-style-type: none"> (a) HCV; (b) HIV-1; (c) HIV-2; (d) HTLV-1; (e) HTLV-2; or (f) syphilis 	ineligible until it has been demonstrated that the person is not infected
24	a person who has potentially been exposed to HBV	ineligible until it has been demonstrated that the person is: <ul style="list-style-type: none"> (a) immune from HBV infection; or (b) not infected with HBV, as confirmed by a nucleic acid amplification test
25	a person who has been a recipient of allogeneic blood, blood components, human derived clotting factors, organs, cells or tissues that did not conform with TGO 88	<ul style="list-style-type: none"> (a) where the person tests negative for HCV using nucleic acid amplification testing—ineligible for at least 4 months from receiving the allogeneic blood, blood components, human derived clotting factors, organs, cells or tissues; (b) in all other circumstances—ineligible for at least 6 months from receiving the allogeneic blood, blood components, human derived

Ineligibility criteria for donor selection		
Column 1	Column 2	Column 3
Item	Medical and social history criteria	Period of ineligibility
		clotting factors, organs, cells or tissues
26	a person who has been imprisoned for a consecutive period of 72 hours or longer	ineligible for 12 months from the date of release from prison
27	a person who works or has worked with animals, in an environment where transmission of zoonotic infections is likely	ineligible for at least 90 days following exposure to the work environment
28	a person who has had chronic therapy with proton pump inhibitors	ineligible for at least 6 months from ceasing therapy
