At BiomeBank we have years of experience manufacturing FMT product from screened donors. Safety is paramount to how we operate and we believe it is important to be transparent about our processes. This is important not only for trust in the product we produce but also when establishing governance around FMT delivery in your institution. We would like to take the opportunity to share with you some key points regarding how we screen our stool donors. If you have any specific questions about the process, you are welcome to discuss this further with one of our physicians.

A key element of our donor screening program is that all donors are regularly screened by an infectious diseases physician or a gastroenterologist with gut microbiome expertise. We believe that this is extremely important due to the complex microbial populations in stool which vary widely between donors and between individual donations from the same donor. Our physicians complete clinical risk-based assessments taking into account local and more distant epidemiological risks, their medical and social history and physical examination findings and this is a vital adjunct to screening tests. These assessments need to be repeated longitudinally as risks can change on a daily basis.

BiomeBank donor screening

KEY POINTS

•            The BiomeBank stool donor eligibility criteria underpins the stool donation program.

o            It is designed to meet the requirements of the Therapeutic Goods (Standard for Faecal Microbiota Transplant Products) (TGO105) Order 2020 and additional risks identified from a literature based risk assessment that take into account both local and more distant infectious disease epidemiologic risks. This is continually monitored and updated at regular intervals.

o            The program is compliant with GMP Manufacturing – Licence to Manufacture Therapeutic Goods, Licence Number: MI-2019-LI-09784-1

•            A potential stool donor must pass a rigorous assessment process to become eligible to enter the stool donation program. This includes:

o            An initial screening questionnaire

o            A thorough clinical assessment by an infectious disease physician or gastroenterologist.

o            Blood, swab and stool testing

            Only those that have passed the clinical assessment proceed to this testing step.

•            The questionnaire, clinical assessment and blood, swab and stool testing are repeated at the beginning and end of each stool donation period .

•            To release FMT product any serology tests must also be repeated at >91 days after the initial blood tests are performed.

o            All stool donated is quarantined until this testing is completed.

•            Within the stool donation period there are processes in place to continually monitor stool donors’ safety and eligibility.

o            On each day of donation, a repeat health assessment in completed including a written questionnaire and general health assessment.

o            Donors are tracked for any illness or exposure risk during a donation period by a donor screening nurse and a physician-based assessment is completed to evaluate ongoing eligibility, repeat testing and impact on any stool already donated.

            Consumption of over-the-counter medications and upper respiratory tract infections are the common triggers for this assessment.

•            At a baseline, the below laboratory tests are performed on all donors.

•            Based on an individual risk assessment, undertaken by an infectious diseases’ physician, additional tests may be required.

Blood

Tests:

•            Complete blood picture

•            Liver function tests

•            C-reactive protein

•            Glucose

•            Human immunodeficiency virus serology

•            Hepatitis B virus core antibody and Hepatitis B surface antigen

•            Hepatitis C virus serology

•            Human T-cell lymphotropic virus type-1/2 serology

•            Syphilis serology

•            Epstein Barr virus IgG

•            Cytomegalovirus IgG

•            Strongyloides species serology

•            Hepatitis A virus total antibody and IgM

•            Serology Archive for TGA

Stool

Tests:

•            Enteric bacterial NAT: Salmonella sp., Campylobacter sp., Shigella/Enteroinvasive E. coli, Enterohaemorrhagic E. coli

•            Enteric viruses NAT: Adenovirus enteric, Adenovirus group F, Norovirus 1 and 2, Rotavirus

•            Enteric parasite NAT: Entamoeba histolytica, Cryptosporidium, Giardia intestinalis

•            Clostridioides difficile NAT faeces

•            Helicobacter pylori antigen faeces

•            Extended spectrum beta-lactamase producing Enterobacteriaceae screen faeces

•            Carbapenem resistant Enterobacteriaceae screen faeces

•            Vancomycin resistant Enterococci screen faeces

Nasal swab

Tests:

•            Methicillin resistant Staphylococcus aureus screen nasal swab

•            SARS-CoV-2 nasopharyngeal NAT weekly while donating

Other epidemiologic risks

The donor screening program is continually re-evaluated against new and changing epidemiologic risks. The emergence of infectious diseases outbreaks, such as Mpox infection and Vibrio parahaemolyticus, emphasise the importance of regular re-evaluation of local and more distant epidemiologic risk. Regular risk appraisal is bespoke to the local donor population and compliments more standardised national or international guidance to enhance safety. To mitigate against these risks our program utilises standardised questionnaires, evaluation by expert physicians and quality risk management assessments of individual key epidemiologic risks. Updates to donor screening program include adjustments to the screening questionnaires and eligibility criteria and in some cases additional testing.

At Biomebank , we remain committed to the supply of quality FMT , produced in a rigorous GMP environment in Australia. If you have any questions or would like further information, please email or call on the details below. You can also visit our website at [www.biomebank.com](http://www.biomebank.com)