



At Novel Biome, we understand that the most critical safety component for all FMT products is appropriate and safe donor screening! This is why we make this our #1 priority, ensuring that we manufacture the highest quality product utilizing extensive donor screening, appropriate medical assessment, and blood and stool testing.

INITIAL DONOR SCREENING

Generally, initial screening excludes a majority of potential donors, with studies suggesting that between 50-and 90% are excluded after medical evaluation. Novel Biome's donor screening is even more selective.

At Novel Biome, we use stringent screening criteria exceeding all published screening standards. We only select donors who are vaginally born, breastfed, active, physically fit, have no history of neurological, psychiatric or neurodevelopmental disorders, eat a diverse omnivorous diet, and all factors known to affect the microbiome.

Novel Biome’s initial donor screening goes above and beyond the standard:

Standard initial medical and health screening	Novel Biome’s initial screening
--	Vaginally born
--	Breastfed
Donor ages range from ≥18 and ≤60 years old	All donors under 30 years of age
General healthy diet	Confirmed diverse omnivorous diet
<3 months use of antibiotics, antifungals, antivirals, immune-suppressants, chemotherapy	Limited lifetime use of antibiotics and antifungals No lifetime use antivirals, immune-suppressants, chemotherapy
--	Never smoked and lives in a non-smoking home (both tobacco and cannabis)
Only recent allergic reactions	No allergies
No travel of 6 months to tropical countries and high-risk areas of communicable disease/ infectious intestinal diseases	No travel for 12 months outside of home country
Inquire about 13 different infectious diseases	Inquire about 34 different infectious diseases
--	No treatment or diagnosis for ADHD and ADD
--	No sleep issues (e.g. insomnia, frequent waking, nightmares)

References: 1.Cammarota et al., 2017, 2. Jørgensen et al., 2017, 3. Australian Regulatory Guidelines of Biologicals, 2020, 4. Cammarota et al., 2019, 5. Mullish et al., 2018, 6. Terveer et al., 2017, 7. Bakken et al., 2011, 8. Kelly et al., 2015, 9. Woodworth et al., 2017, 10. Sokol et al., 2016.

BLOOD AND STOOL TESTING

Once a donor has passed our initial screening, we then apply another set of stringent screening to rule out any possible abnormalities that may be found in blood or stool. All our donors reside in North America and undergo both initial and routine (every 90 days) screening that includes comprehensive testing parameters to evaluate blood and stool, including parasites, viruses, fungi, and active infections, to ensure all collected and processed materials are safe. To best ensure quality and safety, all processed and manufactured stool is first held in quarantine for 90 days to ensure all blood and stool screening passes our standards. For additional safety, we keep a portion of all manufactured samples to ensure in the case of an adverse event, we are able to perform further testing.

DAY OF DONATION SCREENING

Before each donation, our donors complete a current health screening is check for any changes in health that could be potentially harmful to a recipient.

Disclaimer: Novel Biome is a contract manufacturer of FMT products, providing high-quality FMT products to physicians. The information provided in this document should not be considered medical advice and is based on Novel Biome's understanding of their FMT products and past experience treating patients with FMT. Our hope is that this information helps as a starting point for physicians. If you have more questions, comments or concerns with these instructions, please email us at support@novelbiome.com.