FMT QUALITY CERTIFICATE

Mbiotix HBI / MBiotix HBI Caps

Donors are submitted to detailed examinations, interviews, multi-stage qualification procedure and are tested thoroughly at least twice in each donation cycle. Moreover, every sample is subjected to additional quality control on a daily and 5-days period. Products are released after the grace period only if test results for both donors and their samples are correct.

FMT PRODUCTION PROCESS

During production, we ensure proper safety and quality conditions are met. Fresh material must meet the required criteria and has to be delivered to the laboratory within an appropriate time and kept in a safe temperature. The production of the FMT preparations takes place under anaerobic conditions. Our laboratory operates according to the highest standards related to Good Manufacturing Practice (GMP). We conduct detailed molecular, microbiological, cytometric and other tests to characterize our products and to confirm their high quality.

SAFETY

Each material has been subjected to the testing of:

- presence of methicillin-resistant *Staphylococcus aureus* MRSA (culture)
- presence of vancomycin-resistant *Enterococci* VRE (culture)
- presence of rods producing beta-lactamase with an extended ESBL substrate spectrum (culture)
- presence of gram negative rods with acquired carbapenemases (culture)
- presence of adenoviruses, astroviruses, noroviruses, rotaviruses, sapoviruses genogroups I, II, IV, V (PCR)
- presence of *Vibrio* including *Vibrio cholerae* (PCR)
- presence of *Campylobacter jejuni*, *C. coli, C. upsaliensis* (PCR)
- presence of toxin A and B of *Clostridioides difficile* (PCR)
- presence of *Plesiomonas shigelloides* (PCR)
- presence of *Salmonella sp* (PCR)
- presence of *Yersinia enterocolitica* (PCR)
- presence of *Entamoeba histolytica* (PCR)
- presence of *Giardia lamblia* (PCR)
- presence of *Cyclospora cayetanensis* (PCR)
- presence of *Cryptoporidium* (PCR)
- presence of enteroaggregative *E.coli*, EAEC (PCR)
- presence of enteropathogenic *E.coli*, EPEC (PCR)
- presence of enterotoxigenic *E.coli*, ETEC (PCR)
- presence of enterohemorrhagic *E.coli*, including serotype O157, STEC (PCR)
- presence of enteroinvasive *E.coli*, EIEC (PCR)
- presence of SARS CoV-2 (PCR)

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Human Biome

Infectious agents were excluded (during tests at the beginning and the end of the donation cycle):

- active hepatitis A virus infection
- active and chronic infection with hepatitis B virus
- active and chronic infection with hepatitis C virus
- active hepatitis E virus infection
- infection with human immunodeficiency virus (HIV)
- active cytomegalovirus infection and serostatus
- active Epstein-Barr virus infection and serostatus
- infection with *Treponema pallidum* (syphilis)
- *Entamoeba histolytica* infection
- *Strongyloides stercolaris* infection
- active SARS-CoV-2 infection (PCR and ELISA)

In the donor's fecal matter we exclude (during test at the beginning and the end of the donation cycle):

- presence of SARS CoV-2 (PCR)
- presence of *Helicobacter pylori* (immunochromatographic test)
- presence of trematodes, tapeworms, nematodes eggs (microscopic examination of 3 stool samples)
- presence of *Giardia intestinalis* cysts (microscopic examination and PCR)
- presence of *Cystoisospora* cysts (microscopic examination using three stains)
- presence of *Dientamoeba fragilis* (microscopic examination using three stains)
- presence of invasive forms of *Blastocystis hominis* (microscopic examination with the use of three stains)
- presence of microsporidia: *Encephalitozoon* spp., *Enterocytozoon bieneusi* (PCR)
- presence of yeast-like fungi (culture)
- presence of *Salmonella* sp (culture and PCR), *Shigella* sp (culture and PCR), *Yersinia* sp (culture), *Yersinia enterocolitica* (culture and PCR), *Aeromonas* sp (culture), *Plesiomonas* sp (culture), *Plesiomonas shigelloides* (culture and PCR)
- presence of *Vibrio*, including *Vibrio cholerae* (PCR)
- presence of methicillin-resistant strains of *Staphylococcus aureus* MRSA (culture)
- presence of vancomycin-resistant *Enterococci* VRE (culture)
- presence of rods producing beta-lactamase with an extended substrate spectrum ESBL (culture)
- presence of G (-) rods with acquired carbapenemases (culture)
- presence of adenoviruses (PCR and immunochromatographic test)
- presence of enteroviruses (immunochromatographic test)
- presence of astroviruses, noroviruses, rotaviruses, sapoviruses genogroups I, II, IV and V (PCR)
- presence of *Campylobacter jejuni*, C. coli, C. *upsaliensis* (PCR)
- presence of toxins A and B *Clostridioides difficile* (PCR)
- presence of *Entamoeba histolytica* (PCR)
- presence of *Cyclospora cayetanensis* (PCR)
- presence of *Cryptoporidium* (PCR)
- presence of enteroaggregative strains of *E. coli*, EAEC (PCR)
- presence of enteropathogenic strains of *E. coli*, EPEC (PCR)
- presence of enterotoxigenic strains of *E. coli*, ETEC (PCR)
- presence of enterohemorrhagic *E. coli* strains, including serotype O157, STEC (PCR)
- presence of enteroinvasive strains of *E. coli*, EIEC (PCR)

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Human Biome