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Guidelines

Chinese Guidelines on Standardized Technical Specifications for Laboratory Preparation and Quality Control of Fecal Microbiota Transplantation (2026 Edition)

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Abstract

Fecal microbiota transplantation (FMT) has been attempted as an emerging therapeutic tool for a variety of diseases. FMT is an effective method to rebuild intestinal microecology, which refers to transplanting functional flora from healthy human feces into the patient's intestine after treatment to rebuild new intestinal flora and restore the diversity and biological of intestinal flora, so as to realize the treatment of diseases inside and outside the intestinal tract and achieve the purpose of curing diseases. In the field of basic and clinical research targeting FMT, there is a need to recognize and understand the laboratory assays for FMT preparation and quality control. Since there is no unified standard for the experimental procedure and quality management of FMT technology, in order to clarify the standardized laboratory technical specifications for FMT preparation and quality control, the Tumor and Microecology Professional Committee of the Chinese Anti-Cancer Association and the Chinese Infection Immunology and Microecology Research Translation Collaborative Group organized relevant experts to discuss and propose the "Chinese guidelines on standardized technical specifications for laboratory preparation and quality control of fecal microbiota transplantation (2026 Edition)", which provides a basis for further application and in-depth research in the basic and clinical fields of FMT.

Key words: Fecal microbiota transplantation; gut microecology; experimental procedures; quality control; technical specifications; guidelines.

1. Introduction

Fecal microbiota transplantation (FMT), also known as intestinal microbiota transplantation, is an emerging therapeutic approach that has been explored for the treatment of various diseases. FMT is an effective method for reconstructing the gut microbiota, involving the transplantation of processed functional microbiota from the feces of a healthy donor into the patient's gastrointestinal tract. This process helps to establish a new microbiota, restore the diversity and biological function of the gut microbiome, and ultimately treat both intestinal and extra-intestinal diseases, achieving therapeutic goals (1,2).

During the treatment process, the most appropriate method for microbiota administration is chosen based on the patient's condition and the characteristics of various delivery routes. These routes include oral microbiota capsules, as well as administration through nasogastric tubes, nasojejunal tubes, gastroduodenoscopy, colonoscopy, or via ostomy sites using microbiota suspensions. The traditional oral method is simple and cost-effective but may be difficult for many patients to tolerate. Methods involving nasogastric tubes, nasojejunal tubes, and gastroduodenoscopy typically require routine acid-suppressive therapy to reduce gastric acid effects. Furthermore, microbiota suspensions may not reach the distal colon, making these methods unsuitable for patients with colonic diseases, especially those with concomitant bowel obstruction. Additionally, administering through ostomy sites may increase the risk of infections.

A novel FMT route, known as transendoscopic enteral tubing (TET), involves using a standard colonoscope to reach the ileocecal region, where a TET tube is inserted through the biopsy port, and microbiota suspension is delivered through the catheter to the cecum. This method is simpler, more cost-effective, and allows for total colonic

administration, facilitating repeated treatments within a short time frame (3,4).

The efficacy of FMT in refractory or recurrent *Clostridium difficile* infection is well-established, and FMT is now increasingly applied to treat gastrointestinal diseases, neuropsychiatric disorders, hematological diseases, metabolic syndrome, multidrug-resistant infections, and other conditions (5-17). Its application in oncology is also expanding (18-23). FMT has been recommended as third-line therapy for the management of acute gastrointestinal graft-versus-host disease (GVHD) following allogeneic hematopoietic stem cell transplantation (24–27). Several studies have demonstrated that the gut microbiota plays a crucial role in the immune regulation mechanisms underlying GVHD (28-31).

The primary indication for FMT is diarrhea induced by cancer therapies, with no absolute contraindications. However, treatment should be temporarily withheld in patients experiencing active gastrointestinal bleeding, severe neutropenia, or thrombocytopenia. In the field of basic and clinical FMT research, there is a need for a deeper understanding of the laboratory testing methods for FMT preparation and quality control. Given the lack of standardized protocols for the experimental processes and quality control of FMT technologies. Currently, global regulatory frameworks for FMT products remain heterogeneous, and there is no unified consensus on whether FMT should be classified as a biological product, tissue-derived product, pharmaceutical medicinal product, or purely clinical medical technology. Regulatory classification will profoundly shape manufacturing, quality-control, and clinical-implementation requirements, and this topic requires multi-stakeholder deliberation in future regulatory discussions.Against this background, the Cancer Association of China's Oncology and Microecology Committee, in collaboration with the Chinese Infection Immunity and Microecology Research and Translation Group, convened experts to propose the "Chinese guidelines on standardized technical specifications for laboratory preparation and quality control of fecal microbiota transplantation (2026 Edition)." This guideline aims to provide a basis for further research and clinical application in the field of FMT(31).

2. Donor Screening and Management

The safety and efficacy of fecal microbiota transplantation (FMT) depend on the donor. Served as the raw material for FMT production, a stringent donor screening and management protocol is essential to ensure donor biosafety. The process of donor screening and management will involve the privacy information of candidates/donors, and it is necessary to protect the privacy of donors, conduct informed consent of candidates, information desensitization, screening, and management of donors (Figure 1).

2.1 Donor Screening

Donor screening is a highly rigorous process comprising four stages: preliminary questionnaire screening, in-person interviews, comprehensive medical examinations, and medical review. Younger age is generally preferred for candidate donors, yet high-quality evidence directly associating donor age with FMT clinical outcomes remains limited; age-related inclusion/exclusion criteria in this guideline represent expert-opinion-based recommendations and require further prospective clinical validation. To ensure FMT safety, donor screening must adhere to strict criteria that account for the donor's health status, compliance, and the diversity and stability of their intestinal microbiota. Donor health is paramount, requiring the absence of infectious diseases or pathogens that may be transmitted during FMT. Given individual variability in microbiota composition, diversity, and abundance, the stability of a donor's microbiota is influenced by multiple factors. To maximize FMT efficacy, a detailed and multidimensional assessment of the donor's microbiota is necessary (32,33).

2.1.1 Preliminary Questionnaire Screening

A questionnaire is used to assess candidates' dietary habits, sleep patterns, lifestyle, and overall health. Key questions include: ① Regularity of meals, frequency, and extent of sweet or spicy food consumption; ② Frequency of insomnia or late-night activity; ③ Gastrointestinal symptoms (e.g.,), diarrhea, constipation); ④ History of infectious or chronic diseases; ⑤ History of organ transplantation or dialysis; ⑥ Occupational exposure to multidrug-resistant organisms (MDROs); ⑦ Allergies to penicillin or food.

2.1.2 In-Person Interviews

Candidates who pass the questionnaire proceed to the interview stage, which involves: ① Explaining the project and obtaining informed consent; ② Providing an epidemiological survey to assess local outbreaks of infectious diseases; only low-risk candidates proceed; ③ Conducting targeted

inquiries about physical condition, dietary habits, sleep patterns, and lifestyle, and candidates should answer truthfully; ④ After the questioning is completed, the donor candidates are required to fill out a physical health status questionnaire and a mental health assessment questionnaire. The physical health status questionnaire should include at least whether they currently have any serious illnesses or other diseases that affect the gut microbiota (such as irritable bowel syndrome, gastrointestinal bleeding, diarrhea, etc.), medical treatments, medication use, vaccination status in the past 6 months, and whether they have been infected with Helicobacter pylori or have any family medical history.

The mental health assessment questionnaire uses the Symptom Checklist-90 (SCL-90), which consists of 90 items covering a wide range of psychiatric symptomatology. It evaluates aspects such as sensation, emotion, thinking, consciousness, behavior, lifestyle, interpersonal relationships, diet, and sleep. It also reflects psychological symptoms in 10 dimensions through 10 factors.

Exclusion criteria for interviews include: ① Irregular meals, irregular sleep patterns, frequent insomnia, or late-night activity, unhealthy eating habits, such as frequent consumption of sweets, raw food, or processed meats; ② Smoking or habitual alcohol consumption; ③ Chronic diseases, congenital conditions, gastrointestinal diseases, cardiovascular diseases, or a family history of hereditary diseases; ④ Antibiotic use within the past 6 months; ⑤ Work in high-MDRO environments (e.g.hospitals, nursing homes); ⑥ Co-habitants who are healthcare workers or long-term inpatients; ⑦ History of MDRO infections; ⑧ Live-attenuated vaccine administration within the past 9 months; ⑨ SCL-90 score below 50. We emphasize that mental-health screening thresholds, as well as dietary- and lifestyle-associated exclusion criteria in this section, are derived from expert consensus rather than high-level clinical evidence. Correlations between these screening indicators and downstream FMT safety/efficacy remain insufficiently validated. Prospective cohort studies are needed to refine these exclusion thresholds in future revisions.

2.1.3 Comprehensive Medical Examination

Candidates who pass the interview undergo comprehensive testing, including blood and stool analyses, and testing for novel coronavirus and influenza viruses. ① Blood tests include: complete blood count, liver and kidney function tests, seven biochemistry parameters (ALT, AST, urea nitrogen, creatinine, total bilirubin, indirect bilirubin, direct bilirubin), infection panel (Hepatitis B markers, HIV antibodies, syphilis antibodies, Hepatitis C antibodies), lipid profile, rubella virus, cytomegalovirus, magnesium ions, Hepatitis A and E, antinuclear antibodies, Epstein-Barr virus, rheumatoid factor, and T-lymphocyte retrovirus antibodies. ② Stool tests include: routine fecal analysis, calprotectin levels, parasite screening, Helicobacter pylori antigens, MDRO testing (e.g.ESBL-producing Enterobacteriaceae, carbapenem-resistant Enterobacteriaceae, MRSA), and testing for pathogenic bacteria (Clostridioides difficile, Salmonella spp., Shigella spp.), viruses (e.g.,Norovirus, Rotavirus), and parasites (Cryptosporidium).

2.1.4 Medical Review

A medical review program with established standards is essential. Clinical professionals review test results for blood, stool, and pathogen tests. Candidates who pass all stages are added to the donor pool. Screening is only the first step; continuous management of donors in the pool is vital to maintaining FMT safety and efficacy.

2.2 Donor Management

Donor management involves donor health monitoring, donor travel management, donation scheduling, donation validity, and donor release management.

2.2.1 Health Monitoring

Regular follow-ups are necessary to monitor donors' health. Coordinators should communicate with donors weekly to confirm the donor's physical health status over the past week and emphasize reporting any health issues. Non-compliant donors should be re-screened or removed based on the corresponding conditions and selection criteria.

2.2.2 Travel Management

Donors must report travel plans (e.g., for work, vacation, conferences) in advance. Coordinators must evaluate travel-related risks and address them appropriately.

2.2.3 Donation Management

To ensure consistent production and safety, it is necessary to establish a donor donation management program. Donation scheduling should align with production plans. Refer to the donation management mechanism, communicate and negotiate with the donor about the time, location, and precautions for the donation in the case of the donor's donation validity period and regular follow-up without

abnormalities. After sample collection, transport to storage should occur within 2 hours. Post-donation, donors undergo 21 days of health monitoring and record archiving.

2.2.4 Donation Validity Management

A donation validity period of 60 days is defined. Once this period ends, donors must undergo a new round of screening and comprehensive examination to confirm continued eligibility.

2.2.5 Product Release Management

To ensure the safety of the product, it is necessary to reconfirm that each donation is qualified before product release. Qualified donations must meet the following criteria: ① Donations must occur within the validity period; ② Pre- and post-donation MDRO tests must be negative, with a maximum interval of 60 days; ③ Post-donation HIV testing after 21 days must be negative; ④ No abnormalities in daily follow-ups or post-donation health evaluations.

While donor screening and management prioritize safety, analyzing and matching donors' microbiota profiles with recipients' needs is crucial for maximizing FMT efficacy and addressing diverse clinical conditions (33,34).

3. Intestinal Microbiota Analysis

The human intestinal environment contains hundreds to thousands of bacterial species, collectively weighing approximately 1,000 grams. These bacteria are closely associated with daily health and disease conditions in humans. On the one hand, they are shaped by the host's diet and external environment; on the other hand, they participate in physiological processes through various mechanisms, regulating the immune, metabolic, and nervous systems and linking to the physiological functions of systemic organs. To study this complex system, it is essential to identify the bacterial species present in the gut, understand their interactions, and explore their roles in disease progression and recovery (35-37). This information can be obtained through DNA analysis of samples using 16S rRNA amplicon sequencing or shotgun metagenomics, as well as metabolomics analysis of gut microbiota. Due to the difficulty of directly collecting samples from the intestinal tract for microbiota analysis, fecal sample DNA analysis is commonly used as a surrogate for intestinal microbiota assessment in practice (38,39). The results of intestinal microbiota analysis can guide the implementation of FMT. The efficacy of FMT often depends on the characteristics of the disease, the physiological state of the donor and recipient, and their microbiota profiles. Moreover, even for patients diagnosed with the same disease, the underlying pathogenesis and individual characteristics may vary. Therefore, selecting donors and recipients whose microbiota are compatible based on disease characteristics can help maximize the therapeutic effects of FMT(40,41).

At present, the commonly accepted method for analyzing intestinal microbiota is DNA analysis of fecal samples. To understand the microbiota of donors, fecal samples are collected, DNA is extracted, and 16S V4 region sequencing and metagenomic sequencing are performed to analyze the structure, diversity, and metabolic pathways of the microbiota in each candidate. 16S rRNA sequencing is cost-effective, requires less DNA, and involves a relatively simple analytical process. However, the information it provides is limited; it can only identify bacteria to the genus level, lacks resolution for species or non-bacterial microorganisms, and does not provide functional gene information. Instead, it relies on algorithmic models and public databases to make rough functional predictions. Metagenomic sequencing, while more costly, requires slightly more DNA input, and involves complex analytical workflows and higher computational resource demands, provides much richer information. It can identify bacteria, archaea, and viruses at the species or even strain level. Additionally, metagenomic data includes abundant information on functional genes and biosynthetic gene clusters. In practice, the two methods can be combined to balance cost and efficacy. 16S rRNA sequencing can be used as a preliminary screening method, and representative samples can then be selected for in-depth metagenomic sequencing and analysis (42).

It should be noted that unified global standards for microbiota analysis workflows remain absent. Critical variables requiring future standardization include sequencing-platform selection, standardized bioinformatic analytical pipelines, reference-database versions, sequencing-depth thresholds, and multi-level quality-control specifications for raw sequencing reads and assembled data. Inter-laboratory protocol differences may induce analytical result deviations; the microbiota analysis recommendations in this guideline represent best-practice expert suggestions rather than universally validated mandatory criteria.

4. Donor-Recipient Matching Analysis

4.1 Significance of Donor-Recipient Matching

FMT achieves therapeutic effects by reconstructing the intestinal microecology of patients. Although FMT has been applied to numerous indications, its efficacy and mechanisms of action vary significantly across different diseases due to the complexity of its composition and the reliance on donor samples. Research has identified the phenomenon of 'super donors' (43), where certain donors achieve markedly superior therapeutic responses compared to others. Studies have characterized the microbiota profiles of effective donors in conditions such as inflammatory bowel disease (IBD), metabolic syndrome, irritable bowel syndrome (IBS), and recurrent hepatic encephalopathy (44). For instance, an Israeli study using FMT from two donors in combination with anti-PD-1 therapy for melanoma found that all responsive patients were associated with the same donor group (21). From the recipient perspective, individual disease characteristics may involve region-specific or person-specific microbiota-disease interaction mechanisms. To enhance FMT efficacy, it is crucial to optimize both donor and recipient characteristics to achieve the best possible match.

4.2 Overview of Matching Methods

Numerous studies have explored the microbiota characteristics of effective donors. Some researchers have proposed a rational donor selection framework based on disease-specific intestinal microecology features and microbe-host interaction patterns, using microbial or metabolite biomarkers to identify effective donors (45,46). Other researchers have developed predictive models to identify the best donor-recipient pairs. These models incorporate multiple microbiological dimensions, such as alpha diversity, community distance, beneficial and harmful bacteria, as well as functional metabolic pathways. Such predictive models have demonstrated promising results in multinational datasets for ulcerative colitis patients (47).

Despite their value, these studies are often limited by the depth of understanding of microbe-disease interaction mechanisms and the availability of clinical datasets. The development of donor-recipient matching methods can be further advanced by considering the following aspects.

4.2.1 Investigating Disease Characteristics Relevant to FMT

Determine whether the disease is caused by specific pathogenic infections, compromised intestinal barriers, or dysregulated immune, metabolic, or neurotransmitter systems. Explore whether there are distinct disease subtypes and whether these subtypes correspond to different responses to FMT intervention.

4.2.2 Identifying Key Microbes or Functions Associated with Specific Indications

Assess whether key microbes contribute to the production of short-chain fatty acids, improvement of intestinal barriers, regulation of glucose and lipid metabolism, mitochondrial function, or interaction with specific immune cells. Investigate whether relevant microbial products or nutrient metabolism-related gene functions can serve as biomarkers. Identify correlations between specific microbial indicators (e.g.,), enterotypes, diversity) and disease improvement, and examine whether these indicators have causal relationships or mechanisms of action. Use evidence from literature and data to substantiate these relationships and refine donor selection criteria.

4.2.3 Analyzing the Recipient's Intestinal Microbiota

Understand the disease-associated microbial features of the recipient. Assess whether the recipient's microbiota aligns with characteristics of patients likely to benefit from FMT. Identify whether the recipient's intestinal microbiota includes typical disease-associated microbes and functions reported in the literature.

4.2.4 Studying Donor Microbiota Characteristics for Optimal Selection

Select donors based on fundamental attributes (e.g.,), age, gender, BMI, dietary habits) and microbiota features, such as diversity, community stability, and structural integrity. Focus on donors most likely to produce therapeutic effects.

4.2.5 Accumulating Clinical Data and Iteratively Refining Matching Strategies

Continuously collect and analyze clinical data to refine donor and recipient matching methodologies based on treatment outcomes. Evaluate compatibility between specific donor and recipient

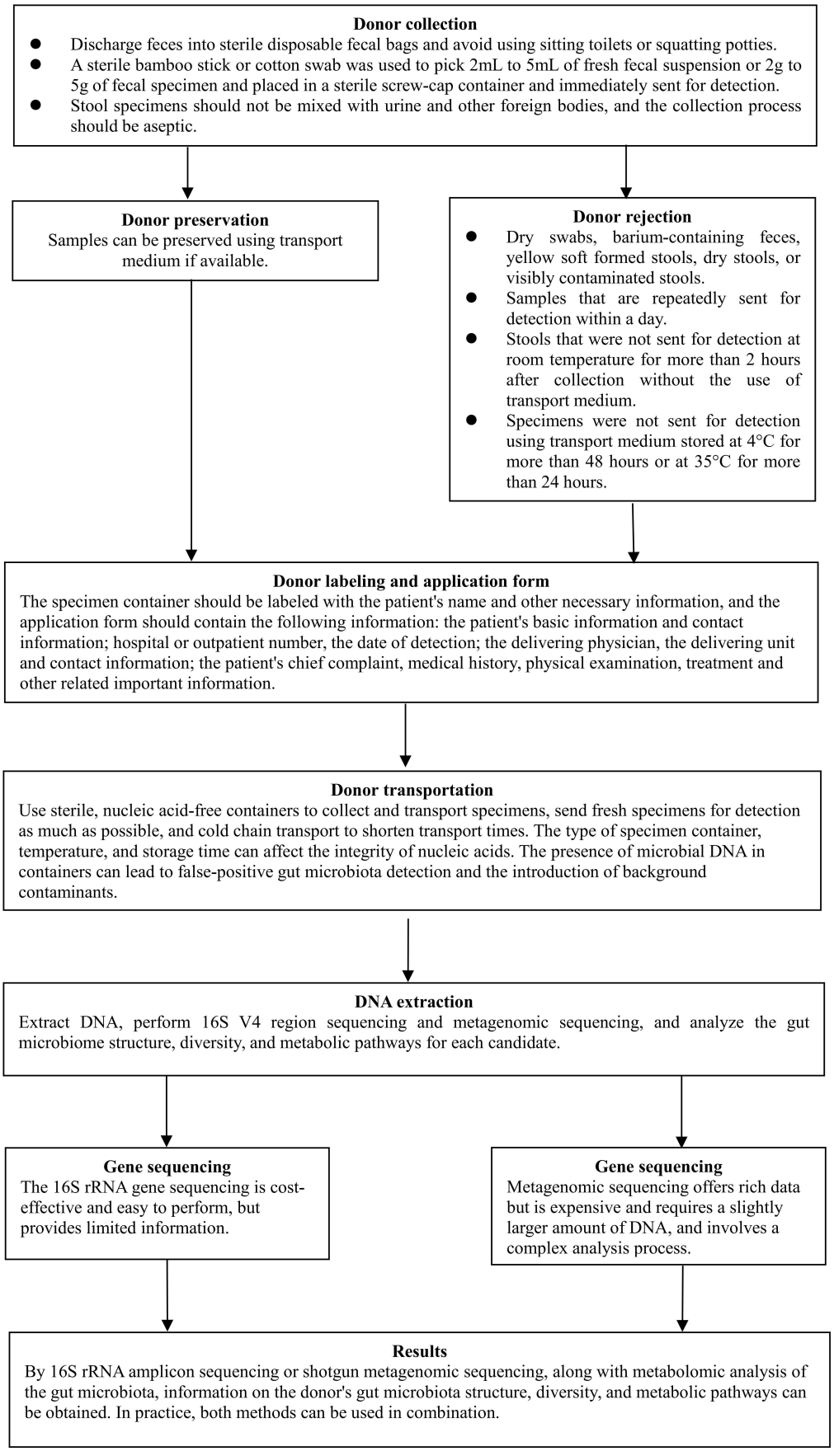


Figure 1. Flowchart of donor collection and laboratory examination.

strains, as well as the colonization potential of donor strains in recipients. Use these insights to guide future donor and recipient selection (48-51). Clinically, we recommend cautious interpretation of donor-recipient matching outputs. At present, evidence is insufficient to support routine universal donor-recipient matching in standard clinical practice. Matching-related analytical approaches remain predominantly research-oriented investigative tools rather than validated clinical-decision-making assays.

5. Requirements for the Preparation and Management of FMT Products

FMT products are typically formulated as frozen microbiota suspensions, frozen capsules, or freeze-dried capsules. There are two primary preparation models for FMT products: ①Direct preparation from fresh stool samples; ②Preparation of frozen stool samples from fresh stool, followed by production of FMT products from the frozen samples (52,53).

5.1 Standard Procedures for Preparing FMT Products

5.1.1 Fresh Stool Samples

Fresh stool samples are inspected for appearance and classified according to the Bristol Stool Chart. Suitable samples are selected, homogenized with appropriate sterile solutions, filtered, and centrifuged to produce concentrated microbiota suspensions. Cryoprotectants are added (or the samples are freeze-dried) to create intermediate products, which are further processed into final products such as frozen microbiota suspensions, frozen capsules, or freeze-dried capsules, followed by packaging (Figure 2).

5.1.2 Frozen Stool Samples

Fresh stool samples are inspected and classified using the Bristol Stool Chart, and suitable samples are treated with sterile cryoprotective solutions. The samples are homogenized and processed into clean, sterile containers, which are then stored in appropriate freezing conditions to produce frozen stool samples. During FMT product preparation, frozen stool samples are thawed (e.g., in a 37°C water bath) and processed through homogenization, filtration, and centrifugation to produce microbiota suspensions. Cryoprotectants are added (or the samples are freeze-dried) to create intermediate products, which are processed into final products and packaged.

5.1.3 Testing and Release

Appropriate sampling and testing are conducted at various stages of preparation in line with risk management protocols. FMT products are released only after confirming that the entire production process, test indicators, and donor health assessments show no abnormalities.

5.2 Key Considerations in FMT Product Preparation

5.2.1 Sterile Collection Containers

Stool samples must be collected in clean, sterile, and sealed containers, with a minimum quantity of 30 grams considered meaningful. Preparation should begin within 6 hours of collection to preserve bacterial integrity, and processing time should be minimized.

5.2.2 Selection of Stool Samples

Stool samples should be classified using the Bristol Stool Chart, selecting types with scores of 3–5. Samples that are overly hard or watery should be avoided.

5.2.3 Sterilization and Sampling

All materials and solutions in contact with stool must undergo sterilization. Sampling during preparation is essential for gastrointestinal pathogen testing and retention.

5.2.4 Batch and Donor Management

The preparation of multiple donor samples or batches in the same location or time should be avoided. When switching donors or batches, the preparation area must undergo thorough cleaning, disinfection, and fumigation to prevent contamination, cross-contamination, errors, or confusion.

5.2.5 Anaerobic Conditions

All stool handling and preparation must occur in a specialized anaerobic environment (oxygen concentration below 0.5%). If a closed system is used, anaerobic conditions must still be maintained. We highlight that the clinical-performance-relevance of this stringent anaerobic-processing threshold still requires further prospective experimental and clinical validation. Direct comparative studies between strictly anaerobic versus partially aerobic processing workflows are needed to quantify impacts on microbial viability and in-vivo therapeutic efficacy.

5.2.6 Storage Stability

FMT products must avoid repeated freeze-thaw cycles during storage and use.

5.2.7 Documentation

Detailed, accurate, and real-time records must be maintained during the preparation process, with documentation archived for at least one year beyond the product's expiration date.

5.2.8 Stability Studies

Stability studies must validate the product's shelf life and ensure its reliability.

5.2.9 Monitoring and Standards

Monitoring programs and acceptance standards must be established for intermediate and final products.

5.2.10 Storage Conditions

Frozen products should be stored at –75° ° C or lower in sealed containers. Freeze-dried products should be stored at –20° ° C or 2–8° ° C, with continuous real-time temperature monitoring.

5.2.11 Anaerobic Microbial Integrity

The gastrointestinal microbiota includes obligate anaerobes, microaerophilic anaerobes, and facultative anaerobes, with obligate anaerobes representing 99% of the total bacterial population. Extreme anaerobes require oxygen levels below 0.5% for survival, while moderate anaerobes can survive at oxygen levels up to 8%. Processing stool under specialized anaerobic conditions better preserves and extracts anaerobic bacterial components. The microbial-viability quantitative thresholds defined are still needed to establish robust correlations between these quantitative cut-offs and actual clinical-treatment outcomes.

5.2.12 Facility Design

Preparation facilities should adhere to the latest Cleanroom Design Guidelines and Pharmaceutical Cleanroom Standards. Static microbial control in exposed processes should meet aseptic control requirements, such as compliance with Grade A of the latest GMP standards (Good Manufacturing Practices).

5.2.13 Quality Management Systems

Commercial entities should follow the latest GMP guidelines or ICH Q10 (Pharmaceutical Quality System) to establish robust quality management systems. Medical institutions should adhere to the latest Preparation Quality Management Standards for Medical Institutions and establish sound quality management systems. All production processes should be supervised and controlled under these systems to ensure that product quality meets the intended standards and clinical requirements.

6. Quality Control of FMT Products

To ensure the safety, efficacy, and stability of FMT products and guarantee their clinical effectiveness, the production of FMT products requires the establishment of dedicated quality control laboratories with corresponding standard operating procedures (SOPs). This includes appropriate personnel, facilities, equipment, and standardized protocols for sampling, testing, and retention. Such measures ensure consistency between raw materials, excipients, packaging materials, process water, production facilities, intermediates, and final products with established standards. Quality control is a critical step in maintaining product integrity and provides an essential technical foundation for FMT applications (48).

6.1 Quality Control of Raw Materials

The primary raw material for FMT is donor stool. As per its biological characteristics, the control measures primarily refer to donor management (detailed in earlier sections). Additionally, stool used for production must undergo gastrointestinal pathogen testing to ensure the absence of pathogenic bacteria, parasites, or viruses. Pathogens to be screened include: Campylobacter (jejuni, coli, upsaliensis), Clostridioides difficile (toxins A/B), Aeromonas hydrophila, Salmonella spp., Shigella spp.Vibrio parahaemolyticus, Vibrio cholerae, Vibrio vulnificus, Yersinia enterocolitica, Enteropathogenic E. coli (EPEC, STEC, E. coli O157, EIEC), Cryptosporidium spp.Rotavirus group A, Norovirus GI/GII, and Adenovirus F40/41. Beyond conventional pathogen detection, we recommend incorporating antimicrobial-resistance-gene screening, resistome profiling, and proactive surveillance for emerging opportunistic pathogens within raw-material quality-control frameworks. At present, standardized testing workflows and clinically actionable threshold values for resistome-related readouts remain to be established; this represents an important direction for future quality-control-method development.

6.2 Quality Control of Excipients and Packaging Materials

During FMT production, excipients such as cryoprotectants, empty capsules, and containers must undergo supplier qualification to ensure material quality. Procedures for procurement, inspection, testing, storage, and distribution must be established. Testing should comply with the Chinese Pharmacopoeia or other national regulations and guidelines. Pharmaceutical-grade materials are

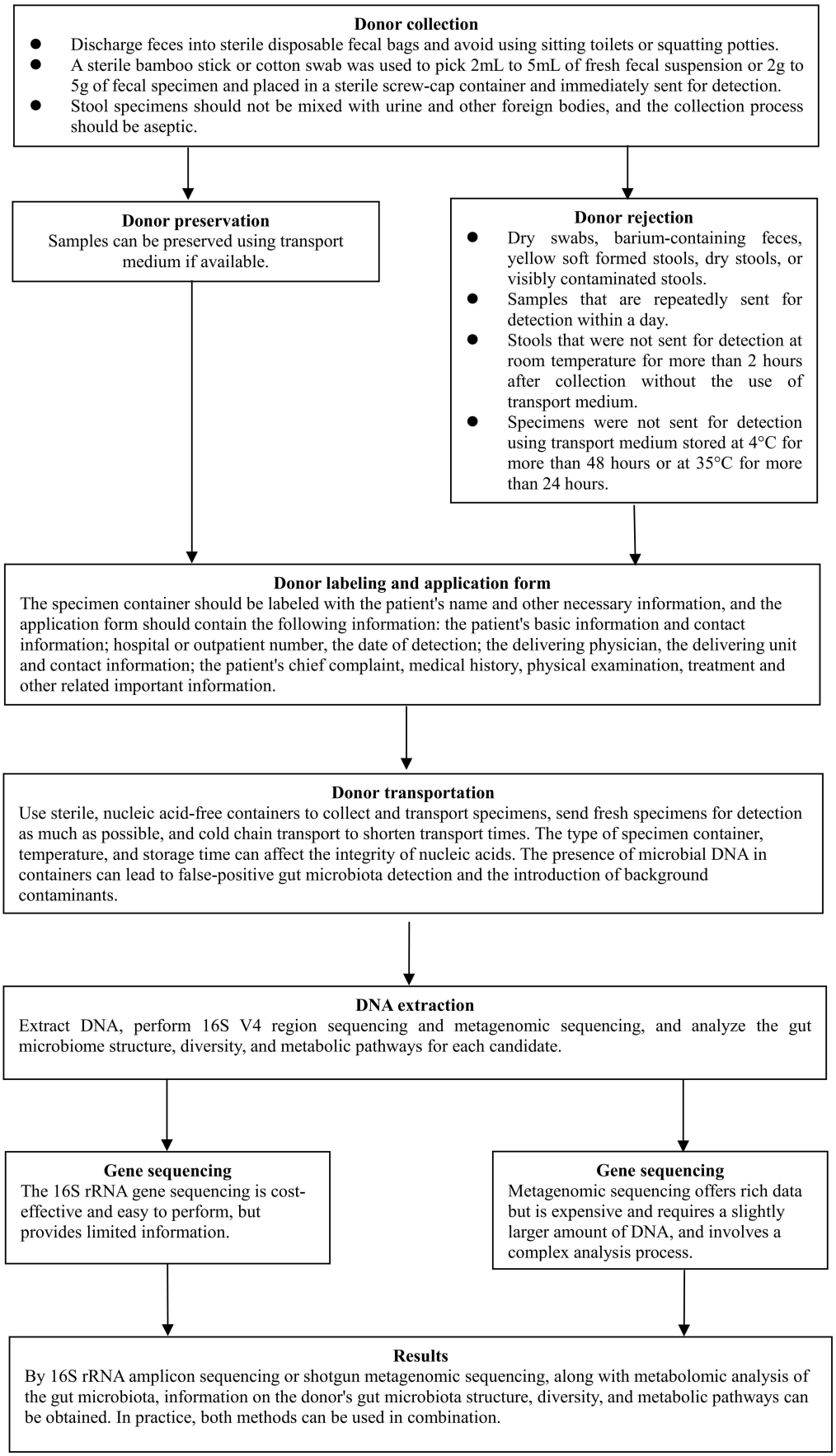


Figure 2. Flowchart of FMT preparation and quality control.

preferred. If pharmaceutical-grade materials are unavailable, a quality risk assessment must be conducted.

6.3 Quality Control of Process Water and Production Facilities

Process water should meet the standards of purified water or higher. Regular testing for attributes such as appearance, pH, nitrates, nitrites, ammonia, conductivity, total organic carbon, non-volatile residues, heavy metals, and microbial limits is necessary. Compliance with GMP and the Chinese Pharmacopoeia is mandatory. If commercially available process water is used, supplier management protocols should be implemented. Production environments must meet the demands of the manufacturing process. Routine monitoring of parameters such as temperature, humidity, differential pressure, airflow velocity, particulate matter, airborne microorganisms, settled microorganisms, and surface microorganisms is required to prevent contamination and ensure compliance with GMP standards.

6.4 Quality Control of Finished Products

Each batch of FMT products must undergo quality testing and documented inspection records. Analytical methods must be validated or follow classical testing approaches to ensure data accuracy and reliability. Common testing parameters in the industry include:

6.4.1 Appearance and Physical Properties

Visual inspection of the product's condition to ensure compliance with predefined standards and absence of abnormalities.

6.4.2 Filling Quantity

To ensure uniformity and stability, products should adhere to labeled quantities as per Chinese Pharmacopoeia requirements.

6.4.3 Disintegration Time

For capsule products, disintegration time should comply with the Chinese Pharmacopoeia. Capsules must fully disintegrate under prescribed conditions, leaving only softened fragments or coatings.

6.4.4 Pathogen Testing

Pathogenic microorganisms such as Campylobacter, Clostridioides difficile, Salmonella spp., Shigella spp., Vibrio spp., E. coli strains, Cryptosporidium spp., and viruses must not be detectable.

6.4.5 Microbial Count

This critical indicator measures product content. Currently, there are no unified or statutory methods for microbial count testing. Common approaches include: ① Culture Method: A classical microbiological testing method. Anaerobic culture is preferred for FMT, measuring colony-forming units (CFU). For bacterial suspensions, viable counts should be ≥1.0E+8 CFU/mL; for capsules, the viable count should be ≥1.0E+8 CFU/g. ② Flow Cytometry: A rapid method analyzing single particles' physical properties, such as size and fluorescence intensity. In FMT, it is used to count viable and total bacterial cells. For bacterial suspensions, viable counts should be ≥1.0E+9 cells/mL; for capsules, viable counts should be ≥1.0E+9 cells/g.

6.4.6 Sample Retention

Key materials and finished products should be retained for up to one year beyond the product's expiration date for quality traceability and investigations. Adequate quantities should be reserved under standard SOPs and periodically inspected. Remark on indication-dependent quality-control requirements: The present guideline provides general-purpose laboratory-preparation and quality-control specifications. Nevertheless, distinct disease indications may require customized FMT-processing workflows and differential quality-control thresholds. Future work should better delineate clinical-application scopes and formulate indication-stratified preparation-and-QC standards grounded in clinical-evidence accumulation.

Declarations

1. ***Consent to publication***
   We declare that all authors agreed to publish the manuscript in this journal based on the signed Copyright Transfer Agreement and followed publication ethics.
2. ***Ethical approval and consent of participants***
   None.
3. ***Disclosure of conflict of interests***
   We declare that no conflict of interest exists in this work.
4. ***Funding***
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5. ***Availability of data and material***
   We declare that the data supporting the results reported in the article are available in the published article and from the corresponding author upon reasonable request.
6. ***Authors' Contributions***
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8. Authors' biography

None.

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