

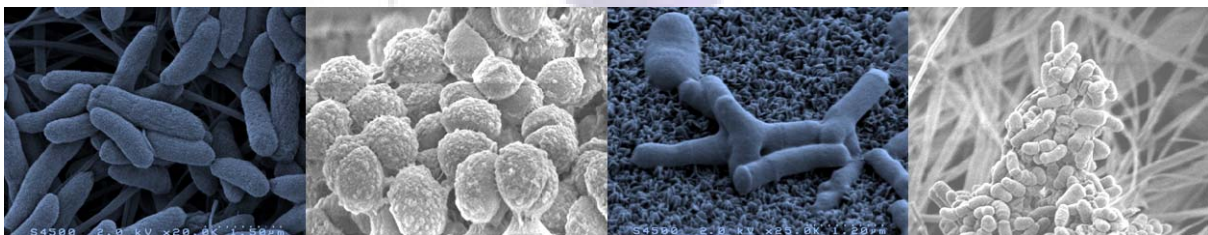


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IHMS – QUALITY PROCEDURE
International Human Microbiome Standards
<http://www.microbiome-standards.org>

**IHMS SOP 02 V1: STANDARD OPERATING PROCEDURE FOR FECAL SAMPLES
SELF-COLLECTION**

LABORATORY ANALYSIS HANDLED WITHIN 4 HOURS ($x \leq 4$ HOURS)



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Introduction

IHMS seeks to coordinate development of standard operating procedures (SOPs) and protocols that will optimize data comparisons in the human microbiome field. The IHMS project concentrates on following objectives:

- Coordinate standardization of procedures and protocols within the existing Human Microbiome research programs and those yet to come,
- Gather and compare the protocols used to collect, identify and process human samples and aid to develop the standard operating procedures for sample collection, identification and processing,
- Compare sequences of genes and genomes of human-associated microorganisms generated by various methodologies and approaches, and to develop standards to define sequence quality and recommend procedures to reach the standards,
- Assess the approaches and procedures used to analyze the sequence data and the associated metadata and recommend standards for data analysis.

Beside these objectives, IHMS project aims at ensuring the optimal public access and use of the data generated by various microbiome projects. The project is supported by the European Commission under the 7th Framework Programme. The consortium gathers 8 partners and 15 contributors across 12 different countries. Its total cost has been evaluated at 2,3 million €, the funding from the European Commission has been set with an upper limit of almost 2 million € and a duration of 4 years, beginning in February 1st, 2011.

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Summary

1.	OBJECTIVE:.....	6
2.	PRINCIPLE:	6
3.	RELATED DOCUMENTS:	6
4.	Persons entitled to use the procedure:.....	7
5.	Preliminary steps, specificities:	7
6.	Conditions and usage constraints to follow:	9
7.	Kit:.....	9
8.	Step by step procedure:	10
9.	Contacts:.....	13

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1. OBJECTIVE:

Optimize data comparisons in the human microbiome field by the standardization of the procedure for fecal samples self-collection.

This SOP is of first interest for good fecal samples collection and conservation practice.

2. PRINCIPLE:

This SOP aims to standardize the fecal samples self-collection in case of the samples to be handled by the laboratory within 4 hours.

3. RELATED DOCUMENTS:

Titles	Codes	Localization
IHMS quality procedure template	IHMS_INS 001 V1	INRA MGP

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4. Persons entitled to use the procedure:

This SOP applies to any person involved in collecting, for good fecal sample collection processing and transportation to the 'laboratory' where it will be handled within 4 hours.

This person can be the person collecting herself, a nurse, or any healthcare agent in charge of stool collection.

5. Preliminary steps, specificities:

Protocol should be approved by an ethics committee according to national regulations. Protocol should be declared on international database (e.g. <https://clinicaltrials.gov>). Volunteers and patients should have signed an informed consent according to approved protocol. Accreditation should have been obtained for sample biobanking, and if necessary for shipping. Anybody wanting to apply this SOP to the fecal samples collection must be in possession of the kit described in this SOP § **Kit**.

A hand washing is mandatory and essential to the preservation of samples quality.

Please note that this SOP applies only to fecal samples collection which will be handled **within 4 hours maximum** by the 'laboratory' in charge of the analysis.

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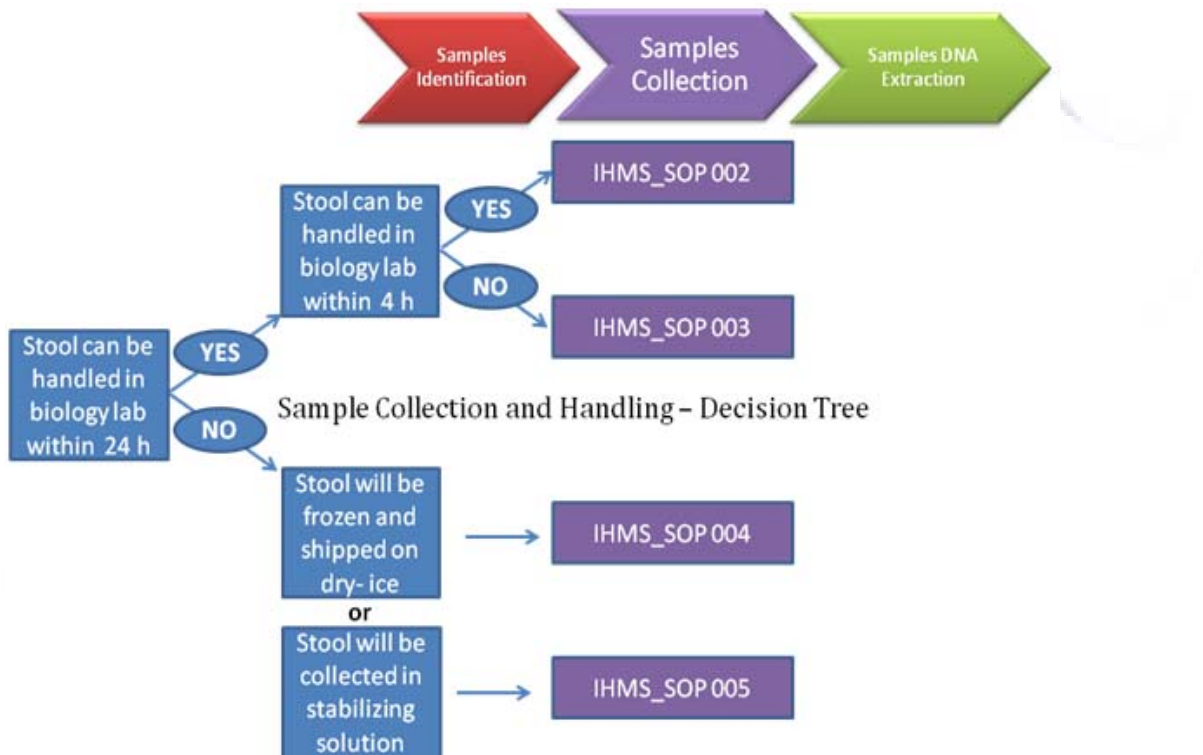
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If it is not your case, please refer to the decision Tree below to select the appropriate SOP for your fecal sample collection:



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6. Conditions and usage constraints to follow:

- 1- Hand washing is mandatory and essential
- 2- The fecal sample minimal volume must be at least the volume of a clementine
- 3- The maximal volume is determined by the volume of the plastic bag (i.) and white pot (ii.)
- 4- The plastic bag (i.) must NEVER be closed
- 5- Close the pot (ii.) tightly with the plastic lid (iii.)
- 6- Stool samples should be kept at room temperature
- 7- Stool samples should be brought to the 'laboratory' within 4 h after collection for aliquoting and storage at -80°C

(i.)*refers to the picture below cf. 8. Step by step procedure

7. Kit:

Materials	Picture 1	Picture 2	Suppliers Names and references
A transparent plastic bag for stool collection (i.)			Stomacher Clearline® ref 140801 Dustcher
A white opaque polypropylene pot (ii.) with transparent lid (iii.)			ref 080866 Dustcher

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8. Step by step procedure:

How to collect the fecal sample (self-collection)?

Numbers correspond to numbers on the attached pictures below:

1. Use the complete kit that you received by mail (see kit's picture below).
It contains :
 - i. A transparent plastic bag for stool collection
 - ii. A white opaque pot to hold the bag
 - iii. A transparent lid to close the pot



Please wash your hands

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2. Insert the transparent plastic bag (i.) by pushing it well in the bottom of the white pot (ii.), with the edges outside the white pot

cf. movie SOP 02 V1 Part 1



3. Pot ready for fecal sample collection



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4. Defecate directly inside the pot (i.)



The fecal sample minimal volume must be at least the volume of a clementine. The maximal volume is determined by the volume of the plastic bag and white pot.

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5. Set the plastic collection bag (i.) containing the stool back into the pot (ii.), **UNCLOSED** cf. movie SOP 02 V1 Part 2



6. Close the lid (iii.) by pressing firmly all the way around the pot (ii.).
Be careful, if the air comes in the sample will be lost
cf. movie SOP 02 V1 Part 2

The samples are **stored at room temperature** and **transported promptly to the « laboratory » within 4 hours (≤ 4 hours)**.

9. Contacts:

If you have any question regarding this SOP please contact us at:

contact@human-microbiome.org

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