Heterogeneity and lack of standardisation in gut microbiome testing: a comparative assessment of French medical biology laboratories

We read with interest the review by de Vos *et al*.[1] The human gut microbiome plays a pivotal role in the maintenance of health and the development of disease.[2 3] With the growing availability of microbiome testing products and publications, some patients feel that their health problems are not fully understood or addressed by doctors using conventional medical approaches.[4] Concomitantly with a rise in consumer interest in self-testing, questions have emerged regarding the scientific validity, regulatory status and clinical interpretability of microbiome testing kits.[5 6] In this context, we aimed to evaluate, on a nationwide French scale, the methods employed, the nature and quality of the results obtained, and the putative benefits that non-specialists/patients can derive from these readily accessible microbiota analyses.

Five French laboratories offering microbiome analysis without prior consultation were selected via standard internet searches by the three microbiology researchers involved in the study, mimicking a patient's approach in June 2024. The patient was a fictitious 40-year-old man, with a normal BMI according to the WHO, no notable medical or surgical history apart from the reason for carrying out the intestinal microbiome, and no dietary particularities. A homogenised stool sample was prepared from a composite mixture of three male individuals from a cardiovascular cohort (in the acute phase of ST elevation myocardial infarction, characteristics in online supplemental table 1), then split and sent to each laboratory according to their recommendations. Kit components, packaging safety, questionnaires, bioinformatic pipelines and final reports were compared.

A high degree of heterogeneity was observed among the selected laboratories. The content of the kits exhibited significant variations, encompassing prescriptions for procedures and instructions for the accurate collection of samples, and a series of promotional materials unrelated to any biomedical activity (online supplemental table 2). Each analysis kit was accompanied by a questionnaire designed to collect demographic, clinical and/or ethical data (table 1), including required consent for research participation. Irrespective of the approach used or the analytical conditions, a multitude of discrepancies were observed between the laboratories in terms of form (report type, length and delay) and the regulatory considerations involved (UN3373 triple-packaging) and in carrying out any medical biology examination in France (identification of a medical biologist by name and indication of subcontracting). Report lengths varied from 9 to 36 pages. No laboratory supplied raw sequencing data and analytical approaches ranged from 16S metabarcoding to shotgun metagenomics, with scant disclosure of pipeline versions or metrics (table 2). Based on alpha-diversity metrics showing biologically implausible variation (ranging from 3.64 to 6.11), interpretations were contradictory, with opposing classifications of 'eubiosis' and 'dysbiosis' and unsubstantiated health claims. Health or dietary recommendations were often non-personalised, citing dubious or unreferenced sources and were reinforced by the recommendation to consult a specialist. The relationship between the medical laboratory and the pharmaceutical company gives rise to concerns regarding a potential conflict of interest (automatic prescription) as well as a risk to patient health (debated therapeutic solutions).

The dual utility of microbiome testing is encouraging for the field, insofar as it demonstrates first, the importance of integrating microbiome considerations into daily clinical practice; second, the need for available information to consumers and medical practitioners.[7] Calling into question the reliability and medical utility of these tests, the study highlights a lack of standardisation, transparency and clinical validation in current microbiome testing kits.[8 9] The resulting incongruency poses risks of misinformation for consumers and challenges for healthcare providers

Table 1 Composition of the kits received

Laboratory	A	B	C	D	E
Composition of the kits received					
► Cost ► Presence of advertising ► Other information	€249.00 Yes –	€208.50 No >6 years old	€204.95 No >4 years old	€199.00 Yes >15 years old	€199.00 No >15 years old
General: birth	Mode/place	Not determined	Not determined	Mode/place	Mode/place
General: breastfeeding	Maternal/artificial/mixed	Not determined	Not determined	Maternal/artificial/mixed	Maternal/artificial/mixed
Clinical information	► Bristol Scale ► Number of stools per day ► Type of digestive symptoms (bloating, diarrhoea, constipation…)	Type of symptoms (digestive and extradigestive; exhaustive list)	Type of digestive symptoms (bloating, diarrhoea, constipation…)	► Bristol Scale ► Type of digestive symptoms (bloating, diarrhoea, constipation…)	► Bristol Scale ► Type of digestive symptoms (bloating, diarrhoea, constipation…)
Familial medical history	Yes/no (exhaustive list)	–	–	–	–
Surgical medical history	Appendicectomy	–	–	Yes/no (exhaustive list)	Yes/no (exhaustive list)
Personal medical history	► Yes/no (exhaustive list) ► Therapeutic consumption (≤3 months ago) ► COVID-19 history (including vaccination) ► Tobacco consumption	► Yes/no (exhaustive list) ► Current therapeutic consumption ► Tobacco consumption	► Yes/no (exhaustive list) ► Therapeutic consumption (≤6 months ago) ► Tobacco consumption	► Yes/no (exhaustive list) ► Therapeutic consumption (≤1 to 3 months depending on the molecule) ► Tobacco consumption	► Yes/no (exhaustive list) ► Therapeutic consumption (≤1 to 3 months depending on the molecule)

Table 2 Results

Laboratory	A	B	C	D	E
Global considerations					
Support	Slides	Text	Text	Text	Text
Length (pages)	36	31	12	9	9
Identification of the medical biologist (MD and/or PharmD)	No	MD	No	PharmD	PharmD
Time to results (weeks)	6	4	8	8	8
Technical considerations					
Personalisation and advice	Yes	No	Yes (partly)	No	No
Technology approach and analytical version	Shotgun metagenomics	Shotgun metagenomics	Change of technology: the reports for V.9.5 are not comparable with the results for V.10.2	Metabarcoding 16S rDNA V3-V4	Metabarcoding 16S rDNA V3-V4
Sequencing platform	Not available	Not available	Not available	MiSeq	MiSeq
Quality parameters					
Total reads	Not available	Not available	Not available	342 855	380 418
Bacterial reads (% of the total reads)	Not available	Not available	Not available	69.46%	69.68%
Specific considerations					
Diversity metrics (unit)	252 (not determined)	3.64 (Shannon Index)	6.11 (Shannon Index)	3.93 (Shannon Index)	3.83 (Shannon Index)
Diversity interpretation	Dysbiotic	Eubiotic	Eubiotic	Eubiotic	Eubiotic
Enterotype	*Bacteroides*	*Bacteroides*	*Ruminococcus*	*Ruminococcus*	*Ruminococcus*
Bacteroides Firmicutes (%)	44.3–34.55	38.82–51.55	52.57–33.60	16.71–69.29	17.62–68.60
Taxonomy (three mains OTUs)	► *Alistipes putredinis* ► *Bacteroides caccae* ► *Escherichia coli*	► *Bacteroides vulgatus* ► *Faecalibacterium prausnitzii* ► *Alistipes* sp	Not available	► *Ruminococcaceae* ► *Lachnospiraceae* ► *Bacteroidaceae*	*Ruminococcaceae* *Lachnospiraceae* *Bacteroidaceae*
Unit	Not available	Not available	Not available	Percentage	Percentage
Escherichia coli	Not available	2.12	4.18 (third quartile)	Not available	Not available
Faecalibacterium prausnitzii	95	7.61	6.72 (first quartile)	5.02	5.49
Akkermansia sp	83	0.09	1.13 (fourth quartile)	0.37	0.16
Data on non-bacterial microorganisms	Not available	Research for protozoa, viruses and fungi: negative	Not available	Not available	Not available
Medical interpretation					
References and advice	► 'Nutritional quality: optimal' ► 'Heart and blood vessel capacity: optimal' ► Recommended diet: 9 pages	► 'Positive impact on systems (particularly cardiovascular pathology)' ► 70 references of variable quality ► 'Reduce consumption of polyphenols and fermented foods'	► 'The test is not intended to diagnose or screen for a disease or pathology' ► 'Don't hesitate to contact us for a list of the dieticians we work with'	'Eubiose without any abnormality, to be checked against the rest of the examination and interpreted by a doctor or health professional'	'Eubiose without any abnormality, to be checked against the rest of the examination and interpreted by a doctor or health professional'
Automatic prescription	Yes	Not available	Yes	No	No

interpreting such data.[10] To address these concerns, enhanced regulatory oversight, method validation and the integration of microbiome science into medical education are imperative.[5] The findings of this study call for coordinated efforts between regulators, industry and academia to improve test reliability and foster trust in microbiome diagnostics.

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