

Caveats to adoption of microbiome-based diagnostics

There are four primary concerns about microbiome based diagnostics:

1. Lack of clear evidence or product standards

There is a general lack of consensus and clarity about how microbiome manipulation may ultimately impact human health and treat different diseases. The microbiome sector is still in its early stages and requires additional clinical data supporting this therapeutic approach. These concerns are prompting questions about the reliability of microbiome-based diagnostic tools.

There are also no clear standards for microbiome-based diagnostics research, technology development and product functionality. Many companies remain cautious in terms of their marketing and business strategies and compromise on claims about a product's capabilities.

2. Undefined diagnostic intervention points

There is no widely accepted consensus among physicians and patients on where and how diagnostic tools should be used for example, as routine tests, upon presentation of specific disease symptoms, or before and after a dietary change. Many patients do not understand how these diagnostic tools work, their underlying technologies and differentiating factors.

3. Lack of available therapeutics targeting the microbiome

A primary argument against use of microbiome-based diagnostics is the lack of FDA-approved microbiome-based therapies.

4. Limited insurance coverage

Microbiome-based diagnostic tools and tests are rarely covered by state or private insurance providers as payers remain uncertain of their clinical value or cost-effectiveness. This forces many patients to pay out-of-pocket.

At present there appears to be more hype than science.