I tried to submit an FDA MedWatch report before, but I am not sure if that went through (I have not received the typical confirmation for including in the MAUDE database yet).

I have also collected additional data since that earlier submission.

Either way, these are the essentially the concerns that I currently have:

1) Several specific **supplement recommendations** are being made by Viome. Those recommendations vary in dosage (as well as sometimes specifying different supplements) for the **2 Viome samples collected and submitted at the same time**.

Again, you can see noticeable differences in 2 collections for the same sample, as well as 3 other subsequent collections:

https://github.com/cwarden45/DTC_Scripts/blob/master/Psomagen_Viome/manually_extracted_analysis/Viome-Supplement_Recommendations.pdf

I know that I have gotten a headache from taking a high dosage of Zinc (from another company, for which I submitted a separate MedWatch report). I was hesitant to test any of the supplement recommendations, but I will submit separate MedWatch reports if I do and I encounter adverse reactions.

Additionally, I think that the number of recommendations seems high. So, I hope somebody with more of a medical background can review this table and guess if this has a non-trivial chance of causing harm (before tested by customers like myself).

2) In general, there are also pathway scores for the **same stool sample** were noticeably different.

You can see the details for those samples / analysis here (including a link to GitHub, with possibly complementary analysis):

http://cdwscience.blogspot.com/2021/12/human-metagenomics-comp-2021-divergence.html

3) There are also food recommendations. I have listed the "Foods to Avoid" below. **Again, please notice the variation in the predictions, and a number of them go against my own experience:**

https://github.com/cwarden45/DTC_Scripts/blob/master/Psomagen_Viome/manually_extracted_analysis/Viome-Foods_to_Avoid.pdf

So, I have not taken any actions based upon these reports (or between collection intervals).

If the formatting submitted through MedWatch is hard to read, then a formatted version of this submission is available here: X