IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Joost Louwagie	Confirmation:	2966
Serial No.:	18/179,945	Group No.:	1634
Filed:	03/07/2023	Examiner:	Ethan C. Whisenant
Entitled:	**FECAL SAMPLE PROCESSING AND ANALYSIS COMPRISING DETECTION OF BLOOD**		

AMENDMENT AND RESPONSE TO NON-FINAL OFFICE ACTION MAILED 07/06/2023

EFS WEB FILED
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This paper is responsive to the Office Action mailed 07/06/2023, with response due by 10/06/2023. Applicant respectfully requests reconsideration in view of the remarks hereinbelow.

The Commissioner is authorized by this paper to charge any fees during the entire pendency of this application, including fees due under 37 C.F.R. §§ 1.16 and 1.17 that may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-4302, referencing Attorney Docket No.: **EXCTD-35239.307**. This paragraph is a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).

Amendment to the Claims begins on Page 2;

Remarks begin on Page 6.

AMENDMENTS TO THE CLAIMS:

This listing of the claims will replace all prior listings and versions of claims in the application:

1. (original) A method of processing a freshly-collected fecal sample without freezing, the method comprising:

    a) collecting a fecal sample from a human subject, wherein the fecal sample is collected at home by the human subject;

    b) in a sealable vessel, combining a first portion of the fecal sample with a stabilizing buffer, and sealing the sealable vessel; and

    c) in a sealable container, combining a second portion of the fecal sample with a solution that prevents denaturation or degradation of blood proteins found in a fecal sample, and sealing the sealable container.

2. (original) The method of claim 1, further comprising delivering the sealable vessel containing the first portion of the fecal sample and the stabilizing buffer and the sealable container containing the second portion of the fecal sample and the solution to a medical diagnostics laboratory.

3. (canceled)

4. (original) A method of processing a fecal sample, the method comprising:

    a) obtaining a pair of portions of a fecal sample collected from a human subject, the pair of portions comprising:

        i) a sealed sealable vessel containing a first portion of a fecal sample and a stabilizing buffer; and

        ii) a sealed sealable container containing a second portion of a fecal sample and a solution that prevents denaturation or degradation of blood proteins found in a fecal sample,

wherein the pair of portions are obtained by the method of claim 1;

b) extracting nucleic acid from the first portion of the fecal sample;

c) testing nucleic acid extracted from the first portion of the fecal sample for an amount of a human nucleic acid; and

d) testing the second portion of the fecal sample for an amount of a blood protein present in the second portion of the fecal sample.

5. (original) The method of claim 4, wherein testing the nucleic acid comprises determining expression from a human gene.

6. (original) The method of claim 5, wherein determining expression from the human gene comprises testing the nucleic acid for presence of human DNA having an epigenetic modification.

7. (original) The method of claim 6, wherein testing the nucleic acid for the presence of human DNA having an epigenetic modification comprises measuring an amount of a methylated human DNA.

8. (original) The method of claim 6, wherein the epigenetic modification comprises aberrant methylation.

9. (original) The method of claim 8, wherein the aberrant methylation comprises hypermethylation.

10. (original) The method of claim 6, wherein the human DNA having an epigenetic modification comprises a gene and/or a promoter region of a gene.

11. (original) The method of claim 10, wherein the gene is selected from the group consisting of *PHACTR3, NDRG4, FOXE1, GATA4, GPNMB, TFPI2, SOX17, SYNE1, LAMA, MMP2, OSMR, SFRP2,* and *CDO1*.

12. (original) The method of claim 6, wherein testing the nucleic acid for the presence of human DNA having an epigenetic modification comprises modifying the nucleic acid with bisulfite ions under conditions wherein unmethylated cytosine is converted to uracil.

13. (original) The method of claim 5, wherein determining expression from the human gene comprises measuring an amount of RNA expressed from the human gene.

14. (original) The method of claim 13, wherein measuring an amount of RNA expressed from the human gene comprises reverse transcriptase polymerase chain reaction (RT-PCR).

15. (original) The method of claim 4, wherein testing for an amount of a blood protein present in the second portion comprises testing for a concentration of hemoglobin in the second portion, wherein a concentration of hemoglobin is indicative of a presence of blood in the fecal sample.

16. (original) The method of claim 15, wherein testing for the concentration of hemoglobin comprises immunochemical detection of hemoglobin.

17. (original) The method of claim 15, wherein the second portion of the fecal sample is considered positive for the presence of blood when the concentration of hemoglobin detected in the second portion is at least 5 ng/ml.

18. (original) The method of claim 15, wherein the second portion of the fecal sample is considered positive for the presence of blood when the concentration of hemoglobin detected in the second portion is at least 10 ng/ml.

19. (original) The method of claim 15, wherein the second portion of the fecal sample is considered positive for the presence of blood when the concentration of hemoglobin detected in the second portion is at least 20 ng/ml.

20. (original) The method of claim 15, wherein the second portion of the fecal sample is considered positive for the presence of blood when the concentration of hemoglobin detected in the second portion is at least 50 ng/ml.

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