The FIDGIT Study

Investigating Fibromyalgia, Digestive function, and the microbiome of the Gastrointestinal Tract.

Sharon Erdrich (PhD Candidate)

Report for [redacted]

DOB: [redacted]

THE UNIVERSITY OF SYDNEY

22 December 2021

Dear [redacted]

Thank you once again for participating in The FIDGIT Study. We appreciate the time you have generously provided in undertaking a range of tests and completing the comprehensive survey. Your contribution is central to gaining insight into the interplay between digestive function, the gut microbiome, and a range of symptoms in women living with fibromyalgia.

On your enrollment to this study, we committed to providing you this report, which includes the results we have been able to make available at the completion of your involvement. These include your diet data, blood chemistry report and the results of your breath tests. As you may recall, the microbiome and environmental samples will be processed collectively, when all participants' samples have been received. This may take several more months to process and analyse, in preparation for publication.

If any of your results are outside the expected range, it is important you consult your health care professional to discuss if any follow up testing or treatment are indicated. If any of your breath tests have been identified as out of range, we advise consulting with a practitioner who is experienced in hydrogen-methane breath test interpretation.

A copy of this report has also been forwarded to your nominated health care provider.

I wish you all the best.

On behalf of the research team,

with kind regards

Sharon Erdrich

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1. Baseline Measures

Date: [redacted]2021

Parameter measured	Reference Ranges	Interpretation	Your Result
Blood pressure (mmHg)	130/80 ≥140/90 ≥160/100	Normal Mild hypertension Moderate hypertension	118/78
Heart rate (beats/minute)	60-100	Normal	94
Height	centimeters		161.4
Weight	kilograms		62.2
BMI (kg/m^2) Note that BMI may not be accurate when a person has high lean muscle mass.	<18.5 18.5 - 24.9 25 – 29.9 >30	Underweight Healthy range Overweight Obese	23.9

BLOOD PRESSURE [1, 2]

It is recommended that at least two blood pressure measurements be taken, at least two minutes apart. Ideally, measurements should be taken from both arms. If the difference between the arms is more than 20 mmHg, the measurements should be repeated. If this difference persists then subsequent measurements should be taken from the arm with the highest reading. Consistent differences in blood pressure measurements of greater than 10 mmHg between arms is associated with increased cardiovascular risk.

Severe hypertension *is defined as a systolic pressure of ≥180 mmHg, or a diastolic pressure of ≥110 mmHg*

Isolated systolic hypertension *is defined as a systolic blood pressure of ≥160 mmHg and diastolic < 90 mmHg, measured in-clinic*

Isolated diastolic hypertension *is defined as diastolic blood pressure of 90 mmHg or higher and systolic pressure of less than 140 mmHg, measured in-clinic*

2. Blood Chemistry

Piccolo Xpress® MetLac 12 Panel – Whole Blood – FASTING

For the blood chemistry analysis, a morning fasting blood sample was taken. Regular medications were taken up until the night before testing and dietary supplements were withheld for 48 hours prior.

Noteworthy is that these measures have been taken as part of a research project, using a Piccolo Xpress®, a Point-of-Care automated clinical chemistry analyser. Reference ranges may vary from community or hospital laboratories, depending on the testing protocols used.

Test date and time: [redacted]2021 10:30

GLU	90	mg/dL
BUN	10	mg/dL
CRE	0.6	mg/dL
NA+	145	mmol/L
K+	4.2	mmol/L
CL-	112	mmol/L
tCO2	28	mmol/L
CA	9.1	mg/dL
PHOS	4.8	mg/dL
MG	2.2	mg/dL
ALB	3.8	g/dL
LAC	1.13	mmol/L

Where the reported values above differ from the usual measures used in New Zealand a conversion to standard NZ laboratory measures has been done, as per the table below[4].

Parameter (REPORT) | (NZ VALUE)		**Ref Range (NZ)**	**Interpretation**	**Your Result**
GLU (mg/dL)	Glucose (mmol/L) *fasting*	< 3.5	Hypoglycaemia	4.95 mmol/L
		3.5 - 5.4	Normal	
		5.5 - 6.0	Borderline	
		6.1 - 6.9	Impaired fasting glucose / 'prediabetes'	
		7.0 or greater	Possible diabetes - repeat test needed	
BUN (mg/dL)	Blood urea nitrogen (mmol/L)	2.5 – 7.85	**Decreased:** low protein intake **Increased:** high protein intake, or impaired renal and metabolic function	3.57 mmol/L
CRE (mg/dl)	Creatinine (umol/L)	53 - 106	Waste product from muscle metabolism. Used to calculate kidney function	53.1 umol/L
NA+ (mmol/L)	Sodium (mmol/L)	128 – 145	**Decreased**: Gastrointestinal loss, poor renal function **Increased:** Dehydration	145 mmol/L
K+ (mmol/L)	Potassium (mmol/L)	3.6 - 5.1	**Decreased:** Gastrointestinal loss, low magnesium, alkalosis **Increased:** Poor kidney function, metabolic acidosis. Adrenocortical insufficiency (with low sodium).	4.2 mmol/L

Parameter *REPORT*	*NZ VALUE*	Ref Range (NZ)	Interpretation	Your Result
CL- (mmol/L)	Chloride (mmol/L)	98 – 108	Important for maintaining pH balance **Decreased:** gastrointestinal losses, metabolic alkalosis, (often w/low sodium) **Increased**: metabolic acidosis, hypertension, dehydration	112 mmol/L
tCO2 (mmol/L)	Total Carbon dioxide (mmol/L)	18 - 33	**Decreased:** Primary respiratory alkalosis or metabolic acidosis (pain, anxiety, high lactate, hyperventilation) **Increased:** Primary respiratory acidosis or metabolic alkalosis (obesity, lung disorder, meds, low K+) *(depends on blood pH – not measured).*	28 mmol/L
CA (mg/dL)	Calcium* (mmol/L)	2.0 - 2.58	**Decreased**: hypoparathyroidism, magnesium deficiency, vitamin D deficiency **Increased**: hyperparathyroidism, excess vitamin D	2.27 mmol/L
Calcium (adjusted)		CA+[0.8*(4.0-ALB)]		2.32 mmol/L
PHOS (mg/dL)	Phosphorus (mg/dL)	2.2 – 4.1	**Decreased:** low intake or absorption, low vitamin D, high calcium, diuretics. **Increased:** high intake/absorption: high vitamin D, high lactate.	4.8 mg/dL
MG (mg/dL)	Magnesium# (mg/dL)	1.6 – 2.3	**Decreased:** gastrointestinal or renal loss, PPI use **Increased**: supplementation in poor renal function	2.2 mg/dL
ALB (g/dL)	Albumin (g/L)	33-55	**Decreased**: losses, inflammation, poor liver function **Increased**: indicates dehydration	38 g/L
LAC (mmol/L)	Lactate (mmol/L)	<2.0	**Increased:** tissue hypoxia (e.g., vascular occlusion), metabolic disorders (e.g., drugs/toxins, thiamine deficiency).	1.13 mmol/L
eGFR	Renal function (female)	[140-age(years)] x weight (kg) x 0.85/[CRE (mg/dL)] x72)	Impaired <60mL/min Equivocal 60-90 mL/min Ideal >90mL/min	140 mL/min

* Reference ranges above apply to total calcium **when serum albumin is normal**, and to **corrected calcium** (adjusted for albumin concentration). Hypocalcaemia may be secondary to magnesium deficiency, which impairs both the release and action of PTH.

Magnesium deficiency causes an inability of the kidney to conserve potassium. Effects of hypermagnesemia include neuromuscular depression, somnolence, and hypotension.

3. FORT/FORD Test

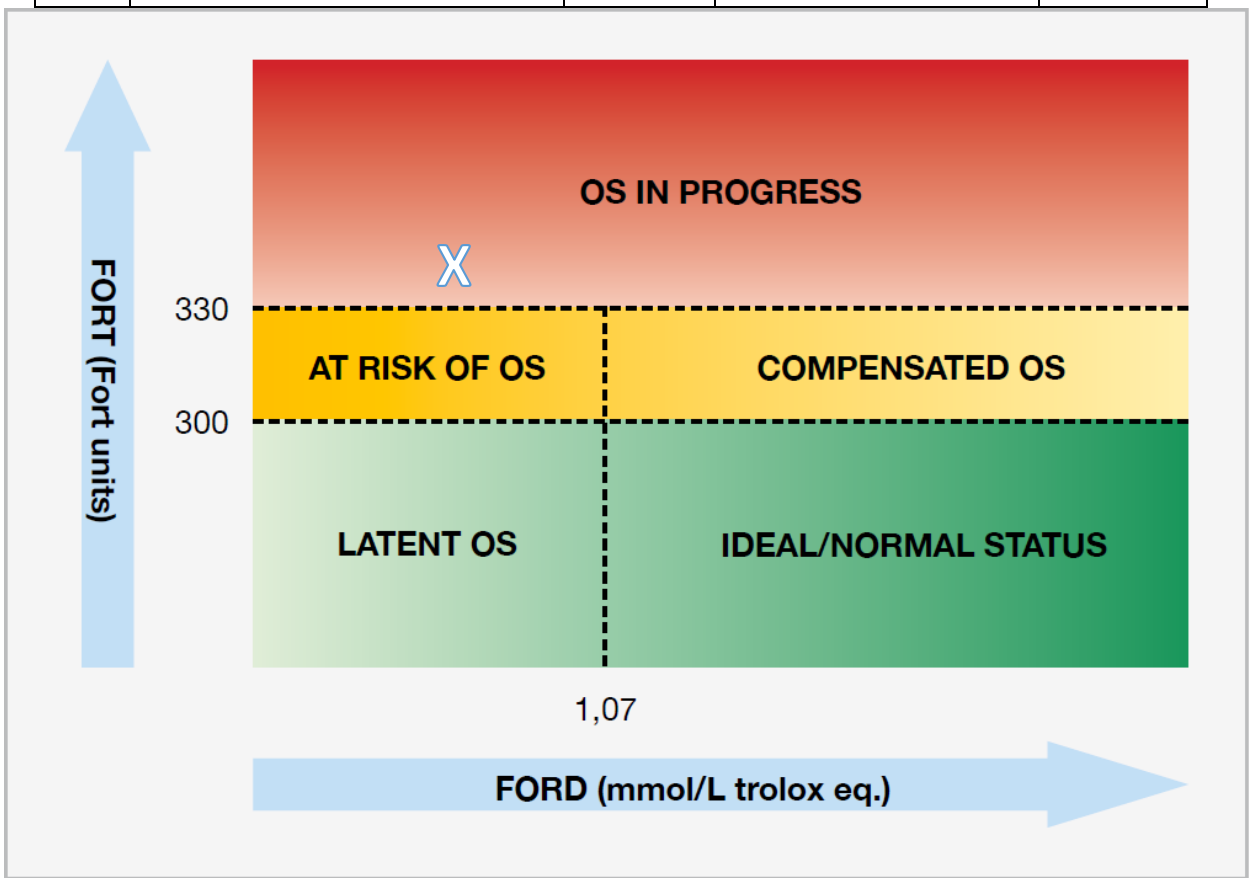
Free Radicals are caused by oxidative stress and cause tissue damage by lipid peroxidation and DNA or protein damage. The innate antioxidant defence system has many components, which are naturally upregulated in response to increased oxidative stress. This test measures both, and they are best viewed in relationship to each other.

FORT: Free Oxygen Radicals Test. This test assesses oxidative stress in a blood sample based on the concentrations of hydroperoxides, utilising the Fenton reaction.

FORD: Free Oxygen Radicals Defence. FORD is an estimation of blood antioxidant capacity, with the water-soluble molecules of ascorbic acid, glutathione, and albumin (but not uric acid), accounting for most of the antioxidant activity. A deficiency in any of these components can cause reduction in the overall antioxidant status of an individual.

Test Date: [redacted] 2021

Parameter		Ref Range	Interpretation	Your Result
FORT	Free Oxygen Radical Test 1 FORT unit = 0.26 mg/L of H2O2.	< 300	**Increased:** High oxidative stress	343
FORD	Free Oxygen Radical Defense (Trolox)	≥ 1.07	**Above ref value**: Ideal **Decreased**: Low antioxidant defences	0.67



Oxidative Stress Index, indicating FORT & FORD results

X indicates your balance of oxidative stress vs innate antioxidants

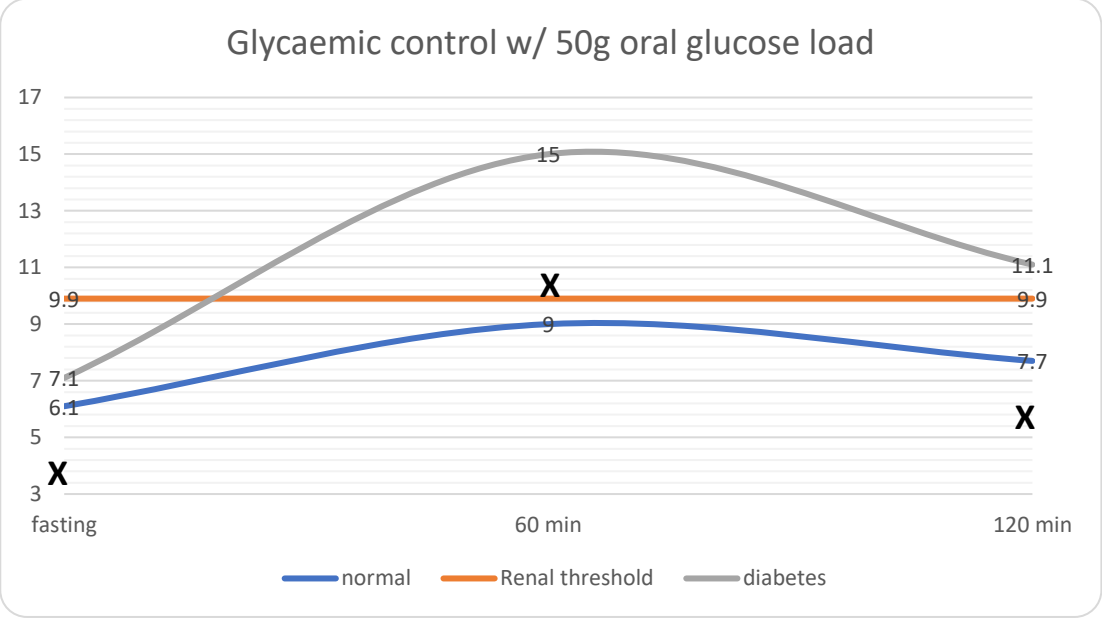
OS=oxidative stress

4. Oral Glucose Challenge

Used to determine the body's handling of a glucose load, the oral glucose tolerance test (OGTT) is usually done using 75g of glucose. For your glucose breath test, 50g of glucose was given, and blood glucose measures taken at baseline (fasting), 60 minutes, and 120 minutes. As interpretative guidelines assume a 75g dose of glucose, these results should be viewed in consideration of the lower dose of glucose administered.

Test Date: [redacted]2021

Time	Values (mmol/L)	Interpretation	Your Result (mmol/L)
BASELINE (fasting)	< 2.8 2.8-3.4 3.5-5.4 5.5-6.0 6.1 – 6.9 > 7.0	Hypoglycaemia Mild hypoglycaemia Normal Borderline Impaired fasting glycaemia Diabetic (repeat test needed)	3.9
1 HOUR			10.4
2 HOURS	<7.8 7.9 - 11.0 >11.0	Normal Impaired glucose tolerance Suspected diabetes	5.6



Oral Glucose Tolerance Curve following 75g Glucose.

X *indicates your blood sugar response following 50g glucose.*

REFERENCES

1. bpac^{nz} Hypertension in Adults: The silent killer (2013) https://bpac.org.nz/bpj/2013/august/hypertension.aspx
2. National Institute for Health and Care Excellence (NICE). Hypertension: clinical management of primary hypertension in adults. London: NICE; 2011. Available from: www.nice.org.uk (Accessed Jul, 2013).
3. Cagnacci, A., Cannoletta, M., Xholli, A. *et al.* Folate administration decreases oxidative status and blood pressure in postmenopausal women. *Eur J Nutr* **54,** 429–435 (2015). https://doi.org/10.1007/s00394-014-0726-8
4. LabPLUS Test Guide https://testguide.adhb.govt.nz/EGuide/

Hydrogen-Methane Breath Testing

Breath testing is a non-invasive diagnostic tool that measures fermentation of specific sugars by the intestinal microbiota.

Three gases are measured. These are hydrogen (H_2) and methane (CH_4), which cannot be produced by humans and are thus excellent measures of fermentation, and carbon dioxide (CO_2), which normally comprises about 6.05 of exhaled alveolar breath. Our equipment (the QuinTron Breathtracker) applies a formula to automatically correct H_2 and CH_4 for the concentration of CO_2.

After establishing baseline H_2 and CH_4 (fasting, following a preparation diet low in fermentable compounds), a challenge substrate is administered, and breath gas samples are taken every 15 minutes for up to 3 hours. The results from each substrate provides different information about the microbial population in the gut.

For the FIDGIT study, three separate breath tests were undertaken, with the following substrates:

1. Glucose (50g)

Glucose is a readily absorbed monosaccharide. Usually, absorption takes place in the first few feet of the small intestine. If bacteria are over-represented proximally, an increase in breath gases may be seen. Any increase ≥ 10 ppm in H_2/CH_4 concentration in two consecutive readings above the basal value following glucose administration is to be considered an abnormal finding.
In the FIDGIT study, capillary glucose was monitored prior to glucose administration and hourly for 2 hours.

2. Lactulose (10g)

A synthetic disaccharide, for which humans have no enzyme capable of degradation, lactulose is typically used as an osmotic laxative. At sub-therapeutic dose (as used for this test), lactulose may determine oro-caecal transit time, confirm colonic hydrogen production and, in some cases, predict proximal bacterial overgrowth. False negatives are also seen, as not all organisms can ferment lactulose. False positives can arise when the substrate is transported rapidly to the caecum.

3. Fructose (25g)

Also a monosaccharide, but less absorbable than glucose, fructose is found in most fruits and a few vegetables. Where fructose is malabsorbed, it is fermented in the caecum and colon can cause significant gas production and may be associated with gut symptoms. Early fermentation of fructose increases the suspicion of proximal bacterial overgrowth, particularly when the early peak either decreases (demonstrating some absorption has taken place), or a is followed by a second peak, consistent with non-absorbed fructose arriving in the large intestine.

References

- WJ Gastro.2014 Jun 28, 2014; 20(24): 7587-7601. doi:10.3748/wjg.v20.i24.7587
- Am J Gastroenterol. 2017 May;112(5):775-784. doi: 10.1038/ajg.2017.46
- United European Gastroenterol J. 2022 Feb;10(1):15-40. doi: 10.1002/ueg2.12133.

Glucose challenge (15 min) Analytical Record

SIBOtest.nz
DIGESTIVE DIAGNOSTICS

Patient: [redacted]
Patient ID: [redacted]
DOB: [redacted]
Weight (at collection): [redacted]
Substrate given: Glucose
Samples collected: [redacted]2021
Samples analyzed: [redacted]2021
Nurse/Technician: [redacted]al, House of Health
Referring physician:

Notes:

Pre-test notes:

Pre-test symptoms:

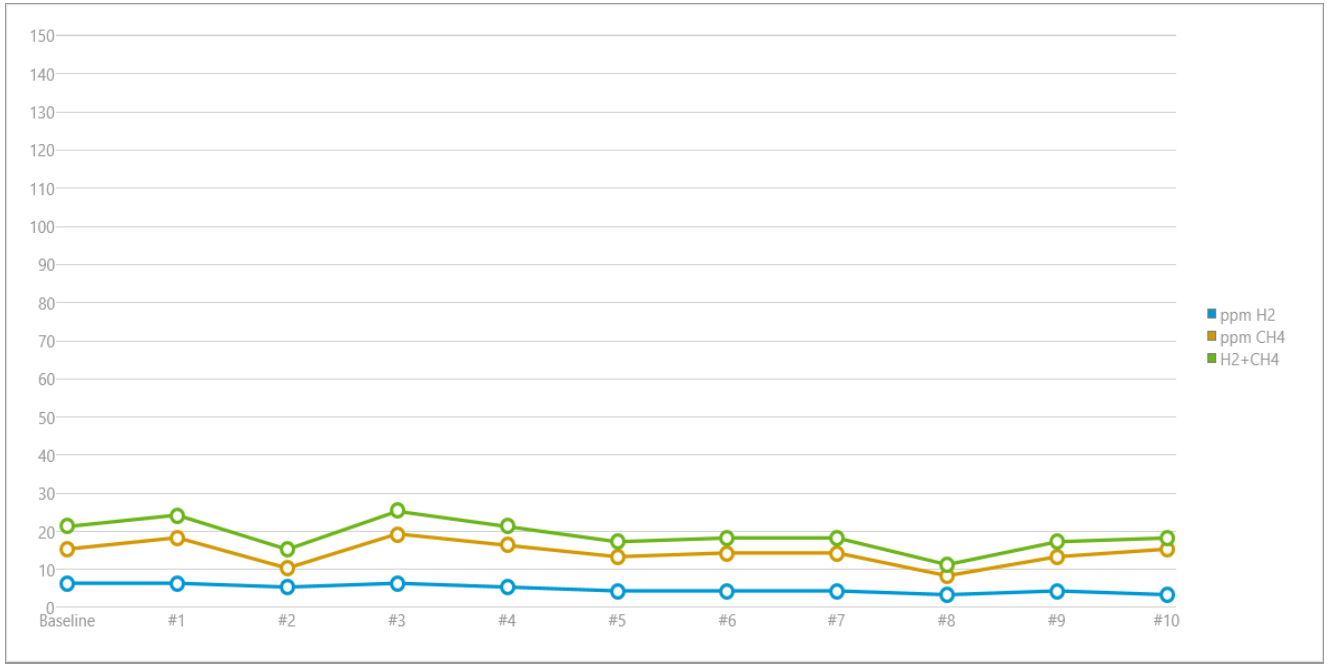
In-test notes:
All samples are valid. Mildly elevated baseline methane suggests colonic fermentation. Glucose 50g after baseline sample.. Symptoms reported during testing.

Diagnosis/Recommendation:

No significant change in breath gases over 2.5 hours of testing. Normal breath test.

Physician Signature:

Date:
08 December 2021



Sample	Time	ppm H2	ppm CH4	ppm H2 + CH4	% CO2	Correction	Symptoms
#0 - 0	8:43 AM	6	15	21	5.3	1.14	
#1 - 15	9:30 AM	6	18	24	5.7	1.07	
#2 - 30	9:45 AM	5	10	15	5.9	1.03	
#3 - 45	10:00 AM	6	19	25	6.3	0.97	Nausea
#4 - 60	10:15 AM	5	16	21	5.8	1.05	
#5 - 75	10:30 AM	4	13	17	5.4	1.12	
#6 - 90	10:45 AM	4	14	18	6.1	1	
#7 - 105	11:00 AM	4	14	18	5.5	1.1	
#8 - 120	11:15 AM	3	8	11	6.4	0.96	
#9 - 135	11:30 AM	4	13	17	6.5	0.94	
#10 - 150	11:45 AM	3	15	18	6.1	1	

DataTracker

Lactulose challenge (15 min) Analytical Record

SIBOtest.nz
DIGESTIVE DIAGNOSTICS

Patient: [redacted]
Patient ID: [redacted]
DOB: [redacted]
Weight (at collection):
Substrate given: Lactulose
Samples collected: [redacted]1
Samples analyzed: [redacted]1
Nurse/Technician: [redacted], House of Health
Referring physician:

Notes:

Pre-test notes:

Pre-test symptoms:

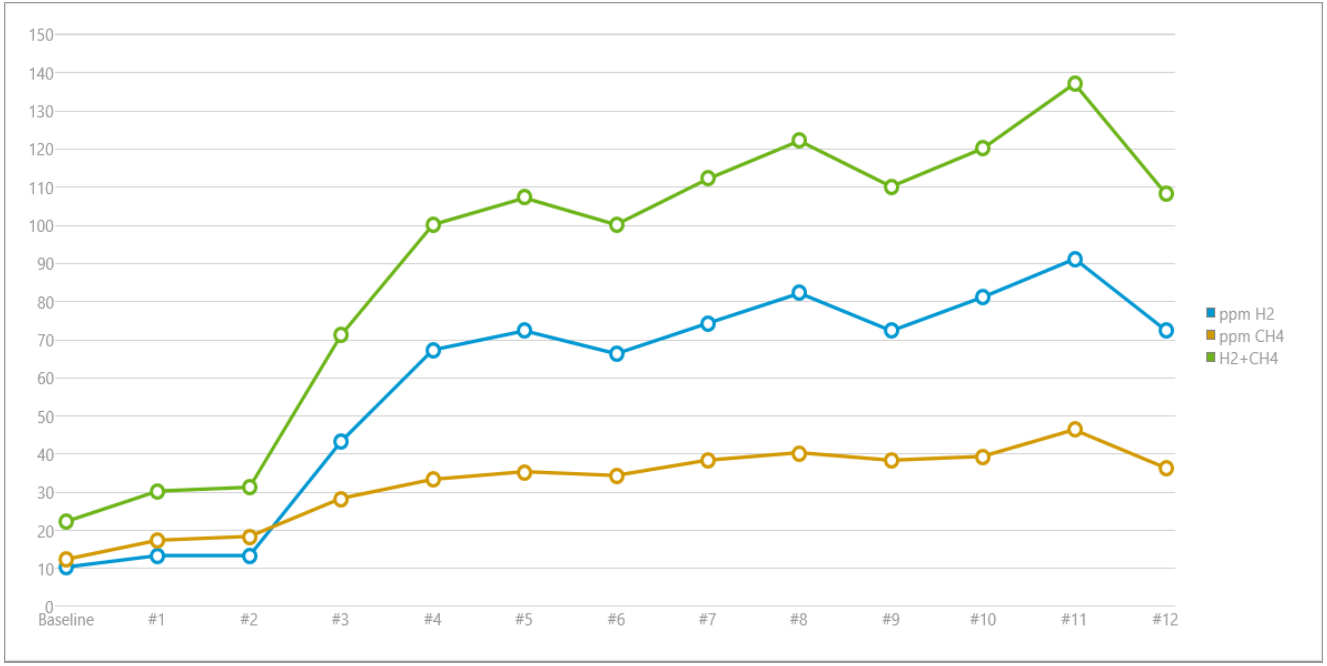
In-test notes:
All samples are valid. Mildly elevated baseline gases suggests ongoing colonic fermentation. Lactulose 10g after baseline sample.. No symptoms reported during testing.

Diagnosis/Recommendation:

Increase of +33ppm hydrogen at 45mins (and +16ppm CH4), with continued increases. In the abscence of symptoms, this may indicate early arrival of lactulose in the colon.

Physician Signature:

Date:
08 December 2021



Sample	Time	ppm H2	ppm CH4	ppm H2 + CH4	% CO2	Correction	Symptoms
#0 - 0	8:38 AM	10	12	22	5.7	1.07	
#1 - 15	8:58 AM	13	17	30	5.3	1.15	
#2 - 30	9:13 AM	13	18	31	5.7	1.07	
#3 - 45	9:28 AM	43	28	71	6.2	0.99	
#4 - 60	9:43 AM	67	33	100	5.6	1.08	
#5 - 75	9:58 AM	72	35	107	6	1	
#6 - 90	10:13 AM	66	34	100	5.5	1.1	
#7 - 105	10:28 AM	74	38	112	5.8	1.05	
#8 - 120	10:43 AM	82	40	122	5.9	1.03	
#9 - 135	10:58 AM	72	38	110	5.4	1.12	
#10 - 150	11:13 AM	81	39	120	5.4	1.12	
#11 - 165	11:28 AM	91	46	137	5.7	1.07	
#12 - 180	11:43 AM	72	36	108	5.5	1.1	

DataTracker

Fructose challenge (15min) Analytical Record

SIBOtest.nz
DIGESTIVE DIAGNOSTICS

Patient: [redacted]
Patient ID: [redacted]
DOB: [redacted]
Weight (at collection): [redacted]
Substrate given: Fructose
Samples collected: [redacted]
Samples analyzed: [redacted]
Nurse/Technician: [redacted], House of Health
Referring physician:

Notes:

Pre-test notes:

Pre-test symptoms:

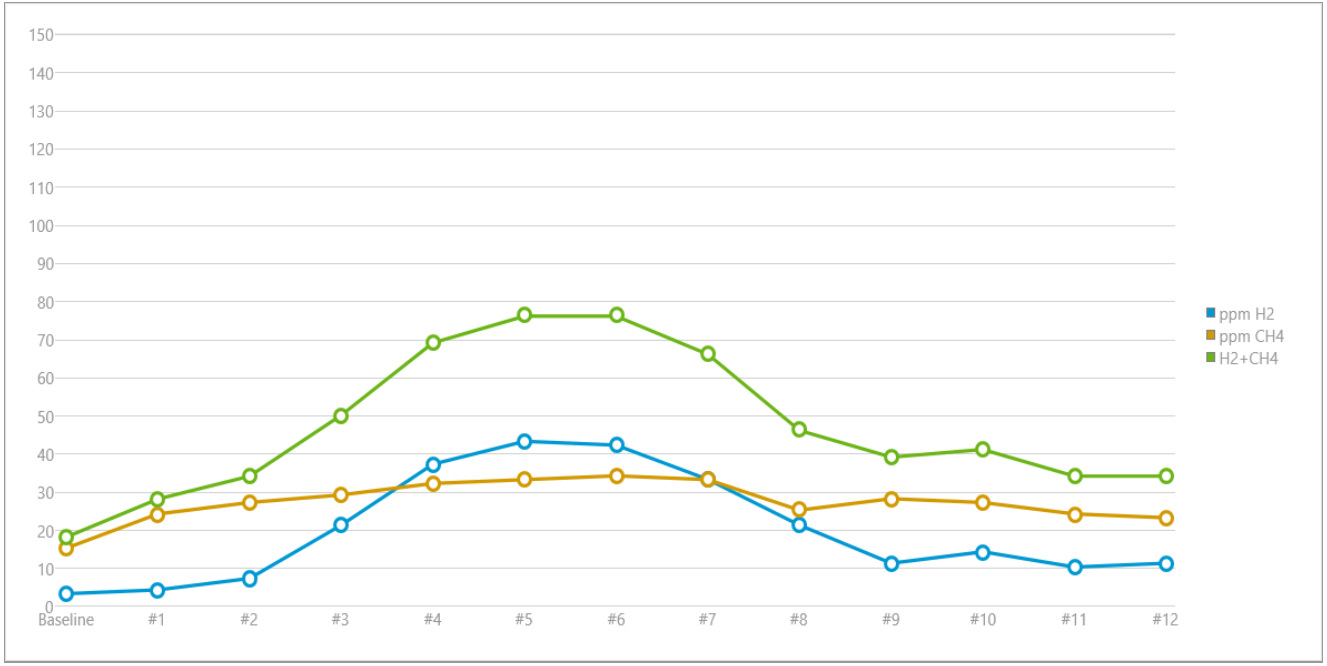
In-test notes:
All samples are valid. Elevated baseline methane. Fructose 25g after baseline sample. Symptoms reported during testing

Diagnosis/Recommendation:

A +34ppm increase in hydrogen is noted at 60 mins, with methane increased by 16ppm. Rises continue through to 90 minutes before decreasing. Bacterial fermentation of the ingested fructose may commence in the small bowel.

Physician Signature:

Date:
08 December 2021



Sample	Time	ppm H2	ppm CH4	ppm H2 + CH4	% CO2	Correction	Symptoms
#0 - 0	8:40 AM	3	15	18	5.4	1.11	
#1 - 15	9:04 AM	4	24	28	5.7	1.07	
#2 - 30	9:19 AM	7	27	34	6	1.01	Bloating
#3 - 45	9:34 AM	21	29	50	5.9	1.03	
#4 - 60	9:49 AM	37	32	69	6	1.01	
#5 - 75	10:04 AM	43	33	76	5.3	1.15	Bloating, Other, Gas
#6 - 90	10:19 AM	42	34	76	5.5	1.1	
#7 - 105	10:34 AM	33	33	66	5.7	1.07	
#8 - 120	10:49 AM	21	25	46	5.1	1.19	Bloating
#9 - 135	11:04 AM	11	28	39	5.5	1.1	
#10 - 150	11:19 AM	14	27	41	5.6	1.08	
#11 - 165	11:34 AM	10	24	34	5.7	1.07	
#12 - 180	11:49 AM	11	23	34	5.6	1.08	

DataTracker

Diet ID
DIET IS A VITAL SIGN

Powered by Diet ID

My Diet ID

[redacted] 2021

DIET ID

Estimated Nutrient Profile

Estimated Calorie Intake

1575

Carbohydrates	207 g	(53% of daily calories)
Total Fat	68 g	(39% of daily calories)
Protein	38 g	(10% of daily calories)

Added Sugars	79 g
Saturated Fat	22 g
Sodium	3182 mg
Dietary Fiber	8 g
Net/Available Carbs	199 g

Cholesterol	186 mg
Total Sugars	89 g

Fats

Monounsaturated Fat	21 g
Polyunsaturated Fat	21 g
Omega-3 Fat	3 g
Trans Fat	2 g

Minerals

Calcium	497 mg
Iron	9 mg
Potassium	1137 mg
Magnesium	126 mg
Phosphorus	709 mg
Zinc	6 mg
Selenium	80 mcg
Copper	1 mg
Manganese	2 mg

Vitamins

Vitamin C	29 mg
Vitamin A	318 mcg
Vitamin D	3 mcg
Vitamin E	8 mg

Vitamin K	88 mcg
Total Folate	326 mcg
Thiamin (B1)	1 mg
Riboflavin (B2)	1 mg
Niacin (B3)	12 mg
Vitamin B6	1 mg
Vitamin B12	2 mcg
Pantothenic Acid	2 mg

HIDE FULL LIST