

Final Report

Patient Information		Sample Information	
Lab Accession:		Sample Type:	
First Name:		Substrate:	
Last Name:		Collected:	
DOB:		Received:	
Sex:		Reported:	
Ordering Physician			
Account No:		Address:	
Physician Name:		City, State:	
Practice Name:		ZIP, Country:	

CO₂ QC Check **Pass**

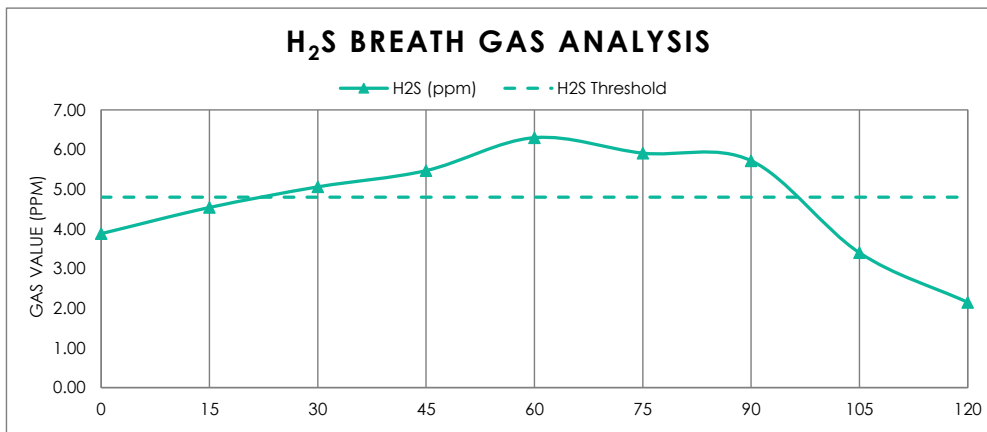
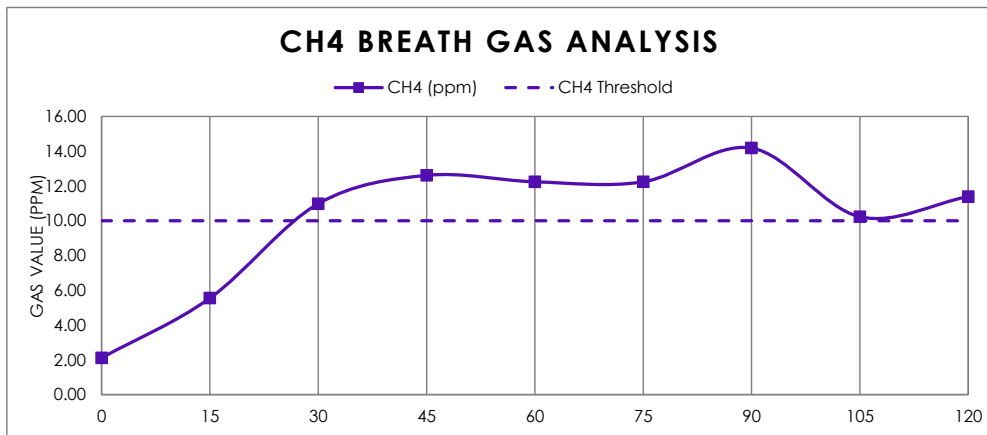
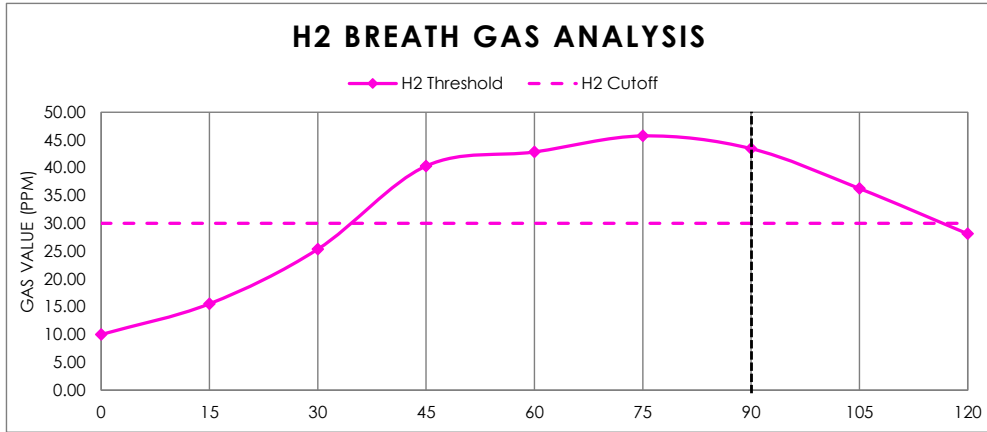
Gases	Expected	Observed	Normal/Abnormal	Interpretation
H ₂ [†]	< 30.02 ppm	45.74	Abnormal	Indicative of Small Intestinal Bacterial Overgrowth, Intestinal Methanogenic Overgrowth, and Excess Hydrogen Sulfide
CH ₄	< 10.00 ppm	14.18	Abnormal	
H ₂ S	< 5.00 ppm	6.30	Abnormal	

[†]Note: The "observed" peak for H₂ must be within the first 90 minutes.

Results									
Gases	T1	T2	T3	T4	T5	T6	T7	T8	T9
H2 (ppm)	10.02	15.55	25.37	40.33	42.86	45.74	43.46	36.28	28.13
CH4 (ppm)	2.11	5.55	10.98	12.61	12.24	12.24	14.18	10.23	11.39
H2S (ppm)	3.88	4.54	5.06	5.47	6.30	5.91	5.72	3.40	2.15
Actual Collection Times									
Time	7:00 AM	7:15 AM	7:30 AM	7:45 AM	8:00 AM	8:15 AM	8:30 AM	8:45 AM	9:00 AM
Interval (min)	0	15	30	45	60	75	90	105	120

eSignature: Shelly Gunn, M.D., Ph.D. 9/18/2020 13:18 PST
 Pacific Diagnostics Lab Director

This test was developed and its performance characteristics determined by Pacific Diagnostics (CLIA: 05D1103594 | CAP 7227931). It has not been cleared or approved by the US Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This laboratory is certified under the clinical laboratory improvement amendments act of 1988 (CLIA-88) as qualified to perform high complexity clinical testing. Final diagnosis will be made by a healthcare professional after reviewing and interpreting the results in correlation with other relevant clinical information. Diagnosis should not be made solely from the results of this test. No final diagnosis is being made by Gemelli or Pacific Diagnostics and shall not be held liable for interpretation of the results or effects or adverse events associated with subsequent treatment. v1.1



About the Assay

Breath testing is an established method for characterizing fermentation patterns in the gastrointestinal tract. The most common use of breath testing is for the assessment of small intestinal bacterial overgrowth (SIBO). Recently, a published North American Consensus assessed the literature supporting the use of breath testing in diagnosing SIBO. A rise of 20 ppm of hydrogen (H_2) by 90 minutes after ingestion of a carbohydrate (glucose or lactulose) is supportive of SIBO.

Methane (CH_4) has also been determined to be an important detectable gas in breath related to intestinal microbial fermentation. Methane is generally produced from conversion of H_2 (by bacteria) to CH_4 by archaea (not bacteria). Methane is noted to be associated with constipation. Higher methane is associated with greater constipation. The North American Consensus further defined abnormal methane as a level at any point during the breath test of ≥ 10 ppm.

trio-smart™ provides the measurement of a third fermented gas, hydrogen sulfide (H_2S). This third gas is produced by sulfate-reducing bacteria utilizing H_2 to produce H_2S . Clinical trials have noted that H_2S is associated with diarrhea in patients. In a recent study, the mean maximum H_2S level was significantly higher in the diarrhea patients (5.99 ± 1.96 parts per million) as compared to constipated (2.14 ± 1.58) and healthy subjects (1.67 ± 1.38 , $P < 0.001$).

Methodology

The trio-smart™ breath test is performed by measuring levels of H_2 , CH_4 , and H_2S in breath of patients collected every 15 minutes after lactulose or glucose consumption. The levels of these gases are compared to breath collected before the lactulose or glucose consumption for reference.

References

1. Rezaie A, Buresi M, Lembo A, et al. Hydrogen and Methane-Based Breath Testing in Gastrointestinal Disorders: The North American Consensus. *Am J Gastroenterol* 2017;112:775-784.
2. Singer-Englar T, Rezaie A, Gupta K, et al. 1089 - A Novel 4-Gas Device for Breath Testing Shows Exhaled H_2S is Associated with Diarrhea and Abdominal Pain in a Large Scale Prospective Trial. *Gastroenterology* 2018;154:S-213.