

FINAL REPORT

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

CO₂ QC Check **Pass**

Gases	Expected	Observed	Normal/Abnormal
H ₂	<30.02 ppm	45.74	Abnormal
CH ₄	<10.00 ppm	14.18	Abnormal
H ₂ S	<3.00 ppm	6.31	Abnormal

Methodology

The trio-smart breath test is performed by measuring levels of Hydrogen (H₂), Methane (CH₄), and Hydrogen Sulfide (H₂S) in the breath of patients collected every 15 minutes after lactulose or glucose consumption. trio-smart follows the recommendations provided by the North American Consensus on Hydrogen and Methane-Based Breath Testing in Gastrointestinal Disorders.

H₂: The "Expected" threshold of H₂ is calculated by adding 20.00 ppm to the baseline (first viable sample). A rise in H₂ levels of \geq 20.00 ppm within 90 minutes is supportive of SIBO. trio-smart reports the "Observed" peak within 100 minutes to account for variability in the sample collection process.

CH₄: The "Expected" threshold for CH₄ is always 10.00 ppm. The North American Consensus defines abnormal levels of CH₄ as \geq 10.00 ppm at any point during the breath test. Elevated levels are associated with constipation.

H₂S: The "Expected" threshold for H₂S is always 3.00 ppm. Levels of H₂S \geq 3.00 ppm at any point during the breath test are considered excess and are associated with diarrhea.

Interpretation

Indicative of Small Intestinal Bacterial Overgrowth, Intestinal Methanogenic Overgrowth, and Significant Excess Hydrogen Sulfide

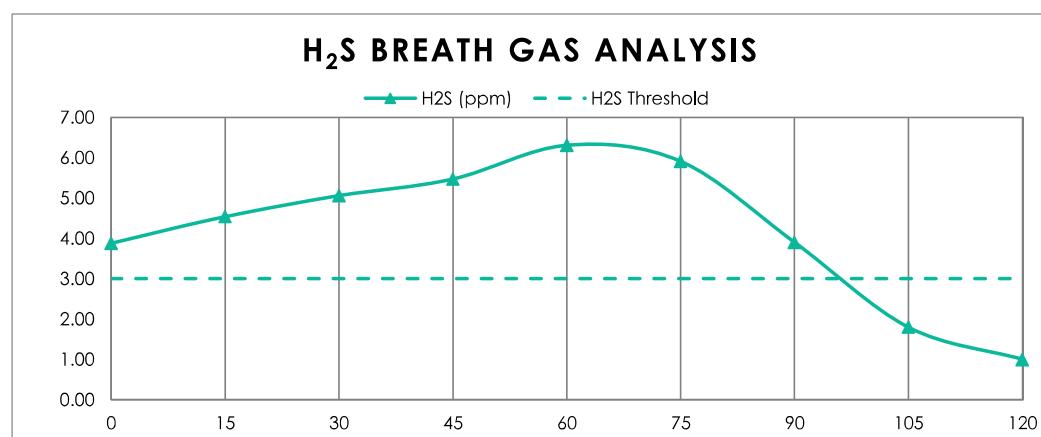
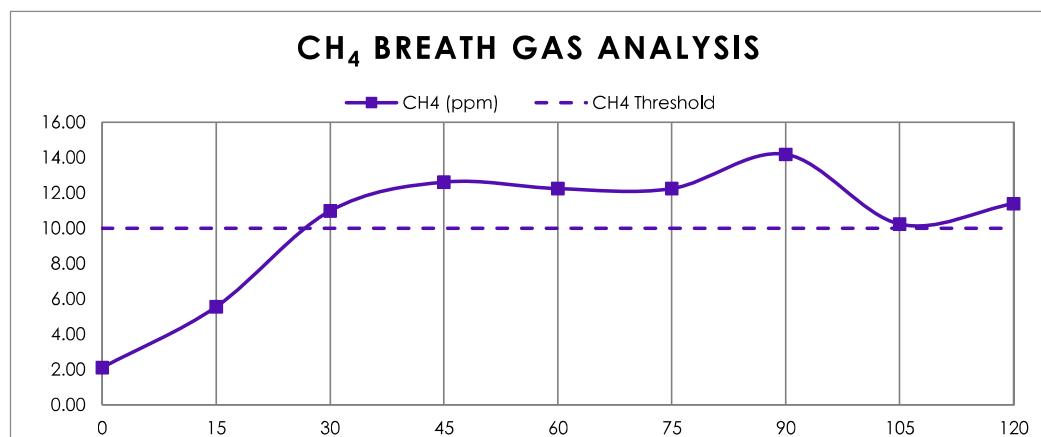
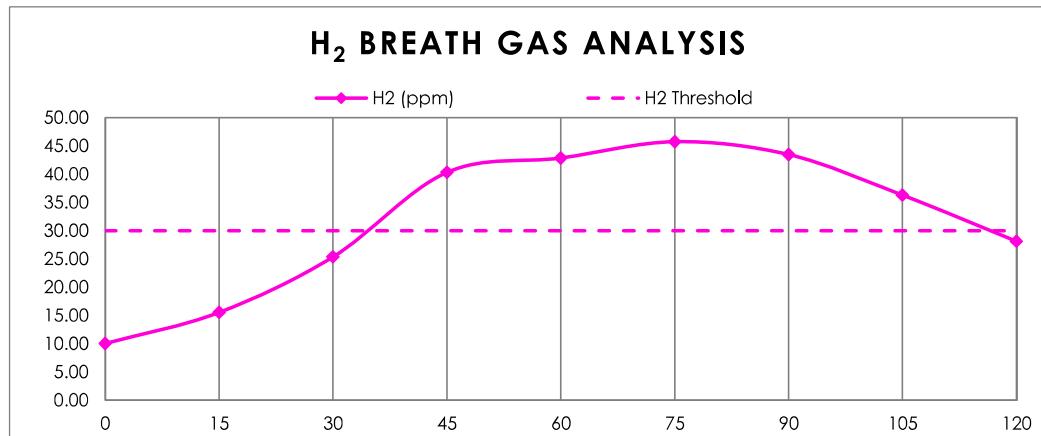
Results									
Samples	T1	T2	T3	T4	T5	T6	T7	T8	T9
Interval (min)	0	15	30	45	60	75	90	105	120
Gases									
H ₂ (ppm)	10.02	15.55	25.37	40.33	42.86	45.74	43.46	36.28	28.13
CH ₄ (ppm)	2.11	5.55	10.98	12.61	12.24	12.24	14.18	10.23	11.39
H ₂ S (ppm)	3.88	4.54	5.06	5.47	6.31	5.91	3.90	1.80	1.00

eSignature: Elizabeth Shelly Gunn, M.D., Ph.D.
 PacificDx Laboratory Director

3/2/2022 10:11 PST

This test was developed and its performance characteristics determined by PacificDx Laboratory (CLIA: 05D2243972 | CAP: 9145700). It has not been cleared or approved by the US Foods 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 PacificDx or Gemelli Biotech and shall not be held liable for interpretation of the results or effects or adverse events associated with subsequent treatment. v2.2

Patient Name:	Physician:	Lab Accession:
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About the Assay

The American College of Gastroenterology Clinical Guidelines for Small Intestinal Bacterial Overgrowth provide authoritative validation of the value of breath testing technology like trio-smart and support mail-in kits with testing in CLIA-certified labs. The North American Consensus on Hydrogen and Methane-Based Breath Testing in Gastrointestinal Disorders establishes common standards utilized by trio-smart.

According to the North American Consensus, a rise of ≥ 20.00 ppm of hydrogen (H_2) within 90 minutes after ingestion of a carbohydrate (glucose or lactulose) is indicative of Small Intestinal Bacterial Overgrowth (SIBO). However, hydrogen does not correlate with symptoms.

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 to CH_4 by archaea (not bacteria). The North American Consensus further defines abnormal methane as a level at any point during the breath test of ≥ 10.00 ppm. Elevated levels of methane are associated with constipation and indicative of Intestinal Methanogenic Overgrowth (IMO). Higher methane is associated with greater constipation.

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, it was found that healthy subjects had H_2S levels of < 3.00 ppm. Levels of hydrogen sulfide ≥ 3.00 ppm are associated with diarrhea and indicative of excess hydrogen sulfide. Higher hydrogen sulfide is associated with greater diarrhea.

References

1. Rezaie, A., Buresi, M., Lembo, A., et al. Hydrogen and Methane-Based Breath Testing in Gastrointestinal Disorders: The North American Consensus. *The American Journal of Gastroenterology*, 2017.
2. Pimentel, M., Saad, R., et al. ACG Clinical Guideline: Small Intestinal Bacterial Overgrowth. *The American Journal of Gastroenterology*, 2020.
3. Singer-Englar, T., Rezaie, A., Gupta, K., et al. Validation of a 4-Gas Device for Breath Testing in the Determination of Small Intestinal Bacterial Overgrowth. *Gastroenterology*, 2018.
4. Pimentel, M., Hosseini, A., Chang, C., et al. Exhaled Hydrogen Sulfide Is Increased in Patients With Diarrhea: Results of a Novel Collection and Breath Testing Device. *AGA Abstracts*, 2021.