

FINAL REPORT

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

CO₂ QC Check	Pass
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Gases	Expected	Observed	Normal/Abnormal
H ₂ †	<30.02 ppm	45.74	Abnormal
CH ₄	<10.00 ppm	14.18	Abnormal
H ₂ S	<5.00 ppm	6.30	Abnormal

†Note: The "observed" peak for H₂ is within the first 90 minutes.

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

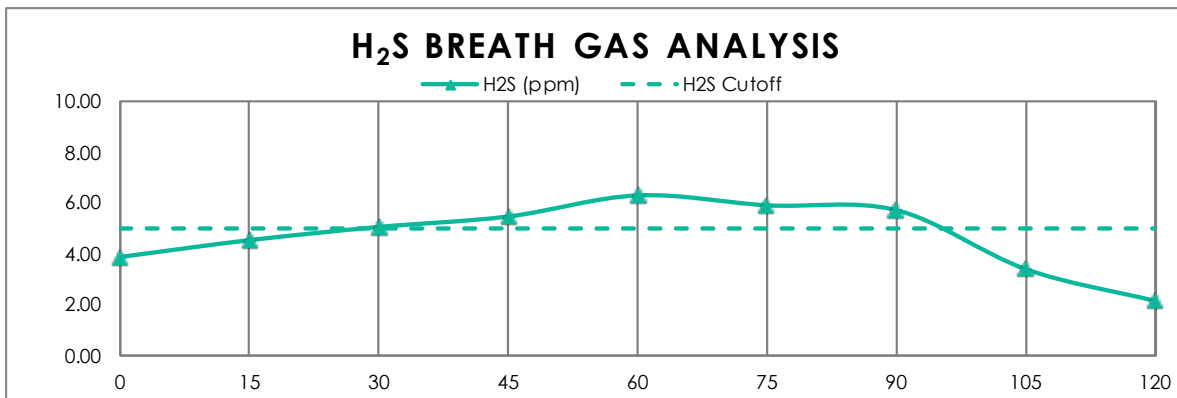
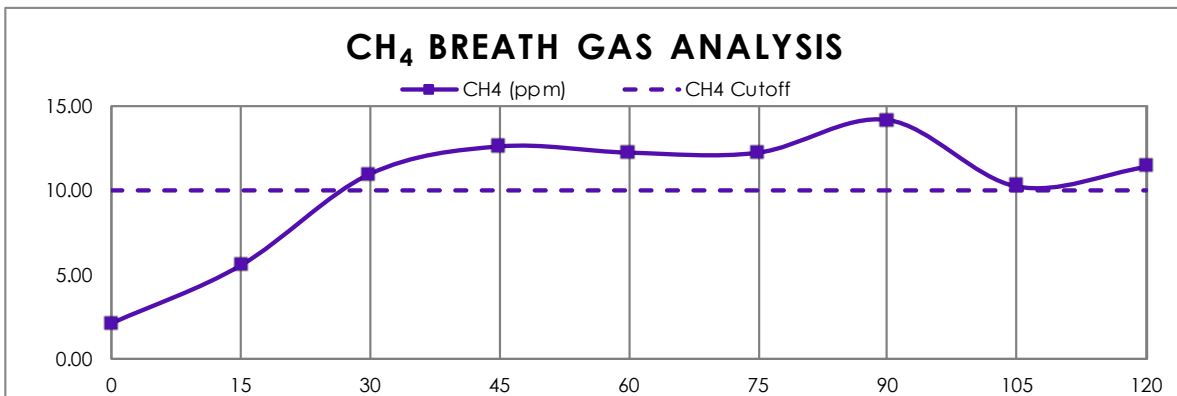
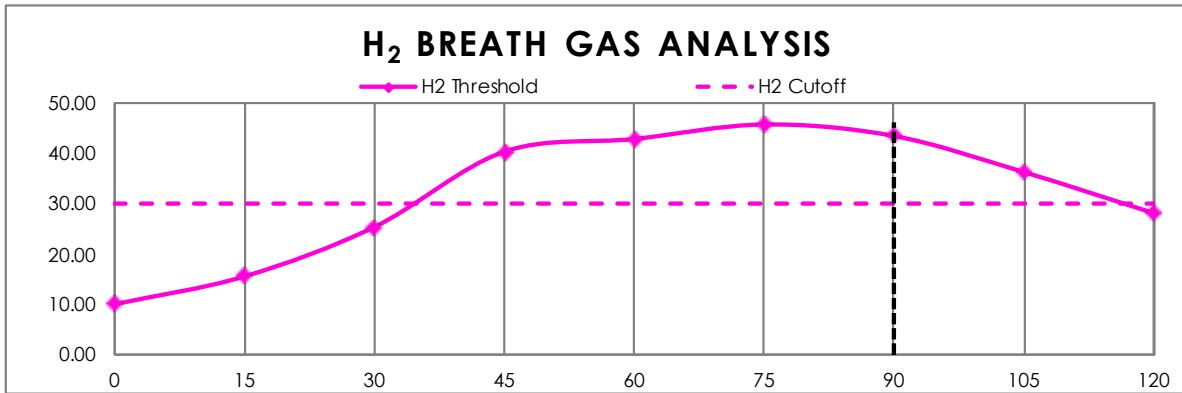
Results									
Samples	T1	T2	T3	T4	T5	T6	T7	T8	T9
Interval (hr:min)	0	15	30	45	60	75	90	105	120
Gases									
H ₂ (ppm)	10.02	15.55	25.37	40.33	42.86	45.74	43.46	36.28	28.13
CH ₄ (ppm)	2.11	5.55	10.98	12.61	12.24	12.24	14.18	10.23	11.39
H ₂ S (ppm)	3.88	4.54	5.06	5.47	6.30	5.91	5.72	3.40	2.15

eSignature: Shelly Gunn, M.D., Ph.D.
 Pacific Diagnostics Lab Director

1/20/21 16:03 PST

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 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 Pacific Diagnostics or Gemelli Biotech and shall not be held liable for interpretation of the results or effects or adverse events associated with subsequent treatment. v2.1

Patient Name:	Physician:	Lab Accession:
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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 Consensus¹ assessed the literature supporting the use of breath testing in diagnosing SIBO. A rise of 20 ppm of hydrogen (H₂) by 90 minutes after ingestion of a carbohydrate (glucose or lactulose) is supportive of SIBO.

Methane (CH₄) has also been determined to be an important detectable gas in breath related to intestinal microbial fermentation. Methane is generally produced from conversion of H₂ (by bacteria) to CH₄ by archaea (not bacteria). Methane is noted to be associated with constipation. Higher methane is associated with greater constipation. The North American Consensus¹ 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 (H₂S). This third gas is produced by sulfate-reducing bacteria utilizing H₂ to produce H₂S. Clinical trials have noted that H₂S is associated with diarrhea in patients. In a recent study², the mean maximum H₂S level was significantly higher in the diarrhea patients (5.99±1.96 ppm) as compared to constipated (2.14±1.58 ppm) and healthy subjects (1.67±1.38 ppm, *p*<0.001).

Methodology

The trio-smart™ breath test is performed by measuring levels of H₂, CH₄, and H₂S 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. - A Novel 4-Gas Device for Breath Testing Shows Exhaled H₂S is Associated with Diarrhea and Abdominal Pain in a Large Scale Prospective Trial. *Gastroenterology* 2018;154:S-213 (Abstr. 1089).