

## 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:

CO <sub>2</sub> QC Check	Pass
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Gases	Expected	Observed	Normal/Abnormal
H <sub>2</sub> †	<30.02 ppm	45.74	Abnormal
CH <sub>4</sub>	<10.00 ppm	14.18	Abnormal
H <sub>2</sub> S	<5.00 ppm	6.31	Abnormal

Methodology
The trio-smart breath test is performed by measuring levels of H <sub>2</sub> , CH <sub>4</sub> , and H <sub>2</sub> S in the breath of patients collected every 15 minutes after lactulose or glucose consumption. trio-smart follows the recommendations of the North American Consensus for Breath Testing.
<b>H<sub>2</sub>:</b> The "Expected" threshold of H <sub>2</sub> is calculated by adding 20.00 ppm to the baseline (first viable sample). A rise in H <sub>2</sub> levels of ≥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.
<b>CH<sub>4</sub>:</b> The "Expected" threshold for CH <sub>4</sub> is always 10.00 ppm. The North American Consensus defines abnormal levels of CH <sub>4</sub> as ≥10.00 ppm at any point during the breath test. Elevated levels are associated with constipation.
<b>H<sub>2</sub>S:</b> The "Expected" threshold for H <sub>2</sub> S is always 5.00 ppm. Levels of H <sub>2</sub> S ≥5.00 ppm at any point during the breath test are considered excess and are associated with diarrhea. Healthy subjects have shown levels of ≤2.00 ppm. Further research is being done to understand the impact of H <sub>2</sub> S levels between 2.00 ppm and 5.00 ppm.

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
<b>Gases</b>									
H <sub>2</sub> (ppm)	10.02	15.55	25.37	40.33	42.86	45.74	43.46	36.28	28.13
CH <sub>4</sub> (ppm)	2.11	5.55	10.98	12.61	12.24	12.24	14.18	10.23	11.39
H <sub>2</sub> S (ppm)	3.88	4.54	5.06	5.47	6.31	5.91	5.72	3.40	2.15

IVR-Insufficient Volume Received

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

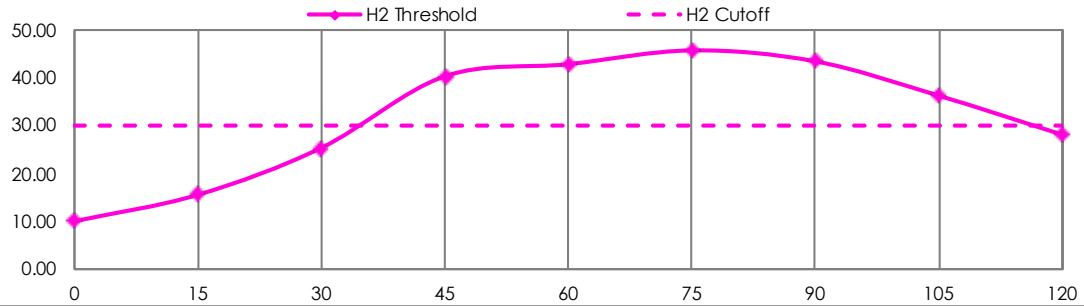
This test was developed and its performance characteristics determined by Pacific Diagnostics (CLIA: 05D1103594 | CAP 7227931). It has not been cleared or approved by the US Foods and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This laboratory is 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:

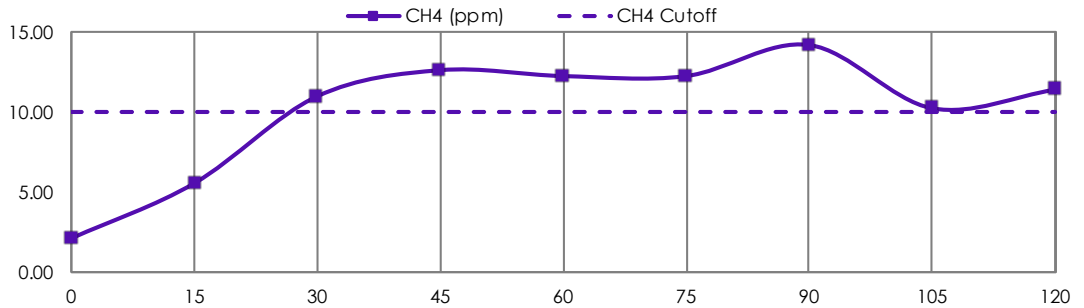
Physician:

Lab Accession:

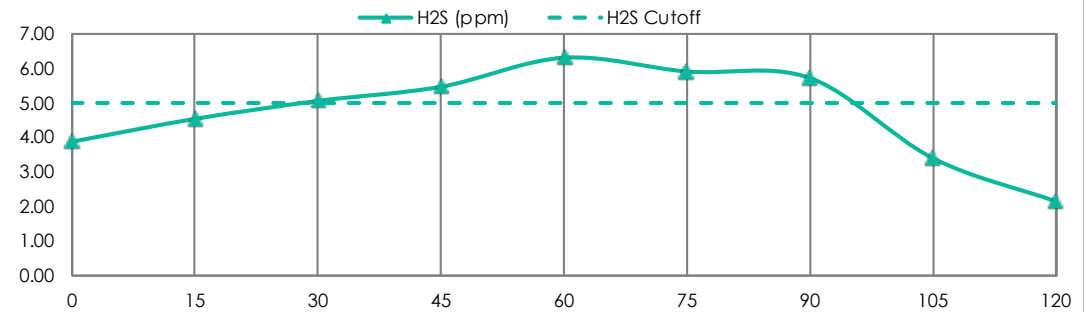
### H<sub>2</sub> BREATH GAS ANALYSIS



### CH<sub>4</sub> BREATH GAS ANALYSIS



### H<sub>2</sub>S BREATH GAS ANALYSIS



**Patient Name:**

**Physician:**

**Lab Accession:**

### 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  $\geq 20.00$  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  $\geq 10.00$  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, the mean maximum  $H_2S$  level was significantly higher in the diarrhea patients ( $5.99 \pm 1.96$  ppm) as compared to constipated ( $2.14 \pm 1.58$  ppm) and healthy subjects ( $1.67 \pm 1.38$  ppm,  $p < 0.001$ ).

### 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.
2. Pimentel M, Saad R, Long M, Rao S. ACG Clinical Guideline: Small Intestinal Bacterial Overgrowth, The American Journal of Gastroenterology 2020.
3. Singer-Englar T, Rezaie A, Gupta K, et al. - 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 (Abstr. 1089).