support@triosmartk	preath.com		P			96	hid	oter
(655) 666-1	Patient	Information			Same			
Lab	Accession:	TrioSmartR	eal		Samp Sample Type	: Breath Ga	s	
1000	irst Name:	test order	- 4 -		Substrate	: Lactulose		
L	ast Name:	Scenario			Collected	: 07/03/2023	3	
DOB: 8/20/1966				Received	: 07/03/202	3		
	Sex:	Female		rdoring Physician	керопес	1: 07/03/202	3	
Ac	count No:	123456789			Address	: Test		
Physic	ian Name:	Asif Multi c	loc		City, State	: New York	NY	
				7IP Country	/: 10001 Unit	ted States of	Americ	
		noemean	Test ruciniy					Americ
		[CO ₂ QC Che	eck Pass]			
	Gases	Expe	ected	Observed	Ν	lormal/Abno	ormal	
	H ₂	<24.35	ppm	24.84	Abr	normal		
	CH₄	<10.00	ppm	33.06	Abr	normal		
	H ₂ S	<3.00 p	opm	2.31	* Se	e Methodolo	ogy and Abo	out the
					A33	uy		
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This test was developed and its performance characteristics determined by Gemelli Biotech Laboratory (2450 W. Broadway Rd. Ste 120, Mesa AZ 85202, CLIA 03D2266739). 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 Biotech. Gemelli Biotech shall not be held liable for interpretation of the results or effects or adverse events associated with subsequent treatment.

Gemelli Biotech Laboratory Director





Patient Name: test order Scenario

Physician: Asif Multi doc

Lab Accession: TrioSmartReq1











Patient Name: test order Scenario

Physician: Asif Multi doc

Lab Accession: TrioSmartReq1

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⁽¹⁾, a rise of \geq 20.00 ppm of hydrogen (H₂) within 90 minutes after ingestion of a carbohydrate (glucose or lactulose) is indicative of Small Intestinal Bacterial Overgrowth (SIBO). Higher levels of hydrogen predict bloating and diarrhea.

Methane (CH₄) is also an important detectable gas in breath related to intestinal microbial fermentation. Methane is generally produced from conversion of H₂ to CH₄ 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 levels of methane predict constipation.

trio-smart measures a third fermented gas, hydrogen sulfide (H_2S). Which 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 2021⁽⁴⁾ study, it was found that healthy subjects had H_2S levels of <3.00 ppm. Levels of hydrogen sulfide \geq 3.00 ppm are associated with diarrhea and indicative of excess hydrogen sulfide. Higher levels of hydrogen sulfide predict more severe diarrhea.

As data continue to accumulate around the increasing importance of H_2S and its relationship to symptoms such as diarrhea and abdominal pain, a 2022 study⁽⁵⁾ demonstrated that in diarrheal IBS patients, $H_2S \ge 2.00$ ppm was notably distinguishable from patients with constipation IBS. This level was also associated with greater H_2S -producing bacteria in the gut. This correlation adds to the growing support for the importance of measuring H_2S . For patients with a level ≥ 2.00 ppm, it is recommended to use good clinical judgment to determine the merit of treatment for this result.

The trio-smart breath test will continue to adapt if and when the evidence supports further changes to the interpretation of the three-gas breath test.

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