

Understanding Your Result Report

Interim Laboratory Director
Andrea Lorraine



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Salem, MA 01970
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Company Contact Information

Test Type

SMALL INTESTINAL BACTERIAL OVERGROWTH (SIBO) RESULT REPORT **10 SPECIMEN LACTULOSE TEST**

Patient Demographics

Patient Name:
Patient Date of Birth:
Patient Address:
Patient City, State, Zip:
Date of Collection:
Specimen Type:

Barcode:

Physician Name:
Physician Address:
Physician City, State, Zip:

Physician Information

Test Date Information

Date Test Received:
Date Test Reported:

Graph of All Sample Values

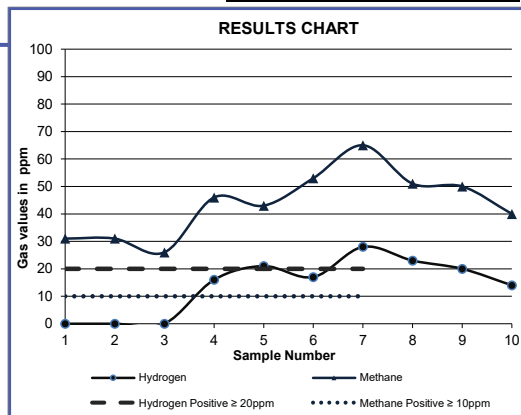


Table of All Sample Values

	Sample Time	Sample Number	Hydrogen ^A (PPM)	Methane ^A (PPM)	Carbon Dioxide (cf)
Small Intestine	Baseline	1	0	31	1.27
	15 min.	2	0	31	1.12
	30 min.	3	0	26	1.08
	45 min.	4	16	46	1.06
	60 min.	5	21	43	1.10
	75 min.	6	17	53	1.13
	90 min.	7	28	65	1.09
Colon	105 min.	8	23	51	1.10
	120 min.	9	20	50	1.11
	135 min.	10	14	40	1.01

^A Hydrogen (H₂) and Methane (CH₄) values have been corrected for Carbon Dioxide (CO₂) content in each sample as a quality assurance measure to ensure sample validity.

* Any Carbon Dioxide Correction Factor (cf) value over 2.50 is considered an invalid sample by the laboratory and is not included in the overall calculations of the test results.

Explanation of CDI's use of a correction factor in the calculations of hydrogen and methane sample values

The highlighted 90 minute mark corresponds to the time that the substrate should transition from the small intestine into the colon.

Explanation that only the samples within the first 90 minutes are compared to the baseline value to indicate the overall test result

Summary of 90 Minute Patient Results

The greatest value for Methane and the greatest difference over baseline for Hydrogen are presented below. If the results of Methane and/or Hydrogen are reported as 0, the combined gas production will be reported as N/A.

Overall Test Results of Each Trace Gas

Hydrogen (H₂) Production:

28

ppm

Normal < 20 ppm over baseline

Methane (CH₄) Production:

65

ppm

Normal < 10 ppm

Combined Gas (H₂ + CH₄) Production:

93

ppm

Normal < 15 ppm

Clinical Cutoff Values to signify a "Supported" Result

¹ Based on the criteria used in this test, the presence of BACTERIAL OVERGROWTH is:

SUPPORTED

Indicator of the Test Result that is either "Supported" or "Not Supported"

COMMENTS:

These test results should be correlated with clinical information that is unavailable to Commonwealth Diagnostics International, Inc. (CDI). For questions and test interpretation, patients/clients should discuss their test results with their healthcare provider. The healthcare provider can assess clinical factors that may affect the interpretation of the test results and ensure that the test results correlate with a patient's symptoms and other related findings for diagnostic and treatment purposes.

This test was developed and its performance characteristics determined by Commonwealth Diagnostics International, Inc. (CDI). This test has not been cleared or approved by the US Food and Drug Administration (FDA), and the FDA does not require this test to go through premarket approval. This test is also listed as exempt on the CLIA edits. This test is used for clinical purposes and should not be regarded as investigational or for research.

Reference 1: Rezaie, A., Buresi, M., Lembo, A., Lin, H., McCallum, R., Rao, S., Pimentel, M. (2017). Hydrogen and Methane-Based Breath Testing in Gastrointestinal Disorders: The North American Consensus. The American Journal of Gastroenterology, 112(5), 775-784.

Reference 2: Pimentel, Mark; Saad, Richard J.; Long, Millie D.; Rao, Satish S. C. ACG Clinical Guideline: Small Intestinal Bacterial Overgrowth, The American Journal of Gastroenterology: February 2020 - Volume 115 - Issue 2 - p 165-178 doi: 10.14309/ajg.0000000000000501

Reviewing Physician

FRM-089 Ver C

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Patient Demographics

Patient Name: [REDACTED]
Patient Date of Birth: [REDACTED]
Patient Address: [REDACTED]
Patient City, State, Zip: [REDACTED]
Date of Collection: [REDACTED]
Specimen Type: [REDACTED]

Barcode: [REDACTED]

Physician Name: [REDACTED]
Physician Address: [REDACTED]
Physician City, State, Zip: [REDACTED]

Physician Information

Test Date Information

Date Test Received: [REDACTED]
Date Test Reported: [REDACTED]

Graph of All Sample Values

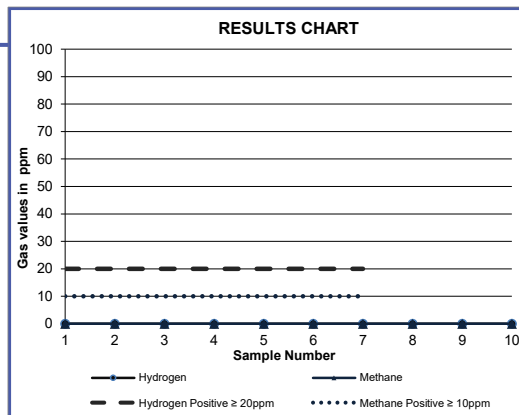


Table of All Sample Values

	Sample Time	Sample Number	Hydrogen ^A (PPM)	Methane ^A (PPM)	Carbon Dioxide (cf)
Small Intestine	Baseline	1	0	0	1.36
	15 min.	2	0	0	1.37
	30 min.	3	0	0	1.34
	45 min.	4	0	0	1.31
	60 min.	5	0	0	1.29
	75 min.	6	0	0	1.20
	90 min.	7	0	0	1.08
Colon	105 min.	8	0	0	1.13
	120 min.	9	0	0	1.12
	135 min.	10	0	0	1.17

^A Hydrogen (H₂) and Methane (CH₄) values have been corrected for Carbon Dioxide (CO₂) content in each sample as a quality assurance measure to ensure sample validity.

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Explanation of CDI's use of a correction factor in the calculations of hydrogen and methane sample values

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Summary of 90 Minute Patient Results

The greatest value for Methane and the greatest difference over baseline for Hydrogen are presented below. If the results of Methane and/or Hydrogen are reported as 0, the combined gas production will be reported as N/A.

Overall Test Results of Each Trace Gas

Hydrogen (H₂) Production:

0

ppm

Normal < 20 ppm over baseline

Methane (CH₄) Production:

0

ppm

Normal < 10 ppm

Combined Gas (H₂ + CH₄) Production:

N/A

ppm

Normal < 15 ppm

Clinical Cutoff Values to signify a "Supported" Result

¹ Based on the criteria used in this test, the presence of BACTERIAL OVERGROWTH is:

NOT SUPPORTED

Indicator of the Test Result that is either "Supported" or "Not Supported"

COMMENTS:

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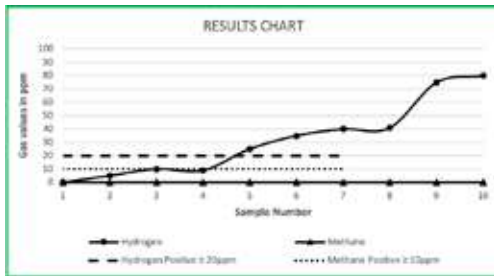
Reference 2: Pimentel, Mark; Saad, Richard J.; Long, Millie D.; Rao, Satish S. C. ACG Clinical Guideline: Small Intestinal Bacterial Overgrowth, The American Journal of Gastroenterology: February 2020 - Volume 115 - Issue 2 - p 165-178 doi: 10.14309/ajg.0000000000000501

Reviewing Physician

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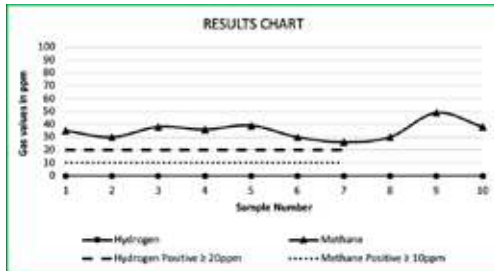
Interim Laboratory Director

COMMON “SUPPORTED” RESULTS



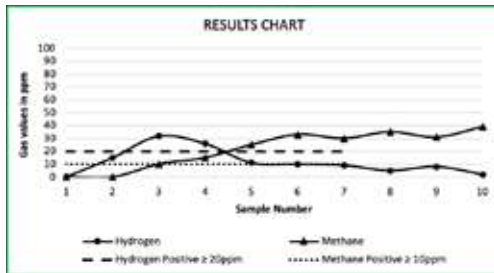
High Hydrogen/No Methane

Patients who have symptoms such as bloating often will have high hydrogen production that increases dramatically throughout the test. Notice that the plot crosses the dashed line at 20 ppm, which indicates a “supported” (positive) result for hydrogen.



No Hydrogen/High Methane

Patients who have symptoms such as constipation often will have high methane production that is present at high levels during the entire length of the test. Notice that the plot is above the dotted line at 10 ppm, which indicates a “supported” (positive) result for methane.



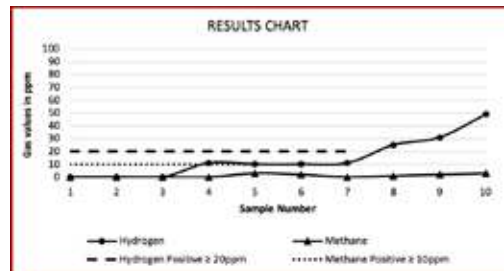
High Hydrogen/High Methane

Patients who produce both methane and hydrogen often demonstrate this plot. This is due to the competing methanogens consuming the hydrogen gas to produce methane gas. The decrease in hydrogen with the increase in methane is indicative of this microbiome composition. This test would be a “supported” (positive) result for both hydrogen and methane.

COMMON “NOT SUPPORTED” RESULTS

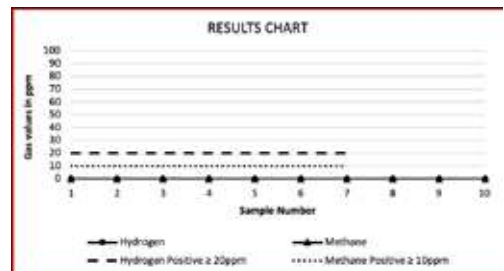
Low Hydrogen/Low Methane

Patients who have GI-related symptoms that do not produce enough gas to surpass the clinical cutoff of either hydrogen (>20 ppm) or methane (>10 ppm) at or before 90 minutes (sample 7) often have this trend. Notice that the two plots do not cross either the dashed line for hydrogen or the dotted line for methane, which indicates the test would be a “not supported” result for either gas production.



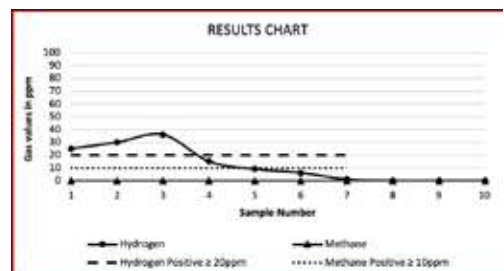
No Hydrogen/No Methane “Flatline Result”

Patients that do not produce any hydrogen or methane throughout the entire test, but still present with GI-related symptoms, often have this plot. This may be due to hydrogen sulfide production from sulfur-reducing bacteria, which a hydrogen and methane breath test cannot detect. This test would be a “not supported” result for either gas. CDI is working with the research community to assess future modalities for diagnostic testing for H₂S (hydrogen sulfide).



High Hydrogen Baseline

Patients who do not fast properly will often have a plot line that looks like this. The first few samples will begin with high hydrogen levels, slightly increase, and then immediately decrease. The patient is recommended to retest when this occurs, this test would be a “not supported” result for either gas.



These common test results are guidelines only and should be correlated with clinical information that is unavailable to Commonwealth Diagnostics International, Inc. (CDI). For questions and test interpretation, patients/clients should discuss their test results with their healthcare provider. The healthcare provider can assess clinical factors that may affect the interpretation of the test results and ensure that the test results correlate with a patient's symptoms and other related findings for diagnostic and treatment purposes.