Understanding Your Result Report

Laboratory Director
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Company Contact Information

Test Type

IBSchek® SAMPLE RESULT REPORT

ANTI-CDTB AND ANTI-VINCULIN TEST

Patient Demographics

Patient Name:	John Doe
Patient Date of Birth:	3/2/1990
Patient Address:	123 Elm Street
Patient City, State, Zip:	Boston, MA 02205
Date of Collection:	01/23/2021
Specimen Type:	EDTA Plasma

Test Date Information

Barcode:	IBS000
Physician Name:	Jane Doe
Physician Address:	573 Longwood Avenue
Physician City, State, Zip:	Boston, MA 02205
Date Test Received:	1/30/2021
Date Test Reported:	01/31/2021

Physician Information

Overall Result for each Biomarker

Clinical Cutoff Values to Signify a "Supported" Result

Analyte Tested	Optical Density (OD) Patient Values*	Reference Intervals
Anti-CdtB (*campylobacter jejuni*)	**3.10** (0.00 0.70 1.40 2.10 2.80 3.50)	Normal < 2.80 OD units
Anti-Vinculin (human protein)	**0.00** (0.00 0.84 1.68 2.52 3.36)	Normal < 1.68 OD units

*OD values are corrected for nonspecific IgG antibody binding within the patient sample

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

✓ Patient results are **supportive** of a diagnosis of either diarrhea predominant or mixed Irritable Bowel Syndrome (IBS-D or IBS-M).

○ Patient results are **not supportive** of a IBS-D or IBS-M diagnosis but may benefit from further testing to evaluate other bowel diseases.

Additional Clinical Information on Result Interpretation

Result Interpretation [1,2,3]

A "supportive test" is confirmed when *either* antibody (anti-CdtB or anti-vinculin) level is greater than the indicated reference intervals. A "not supportive" test is confirmed when *both* antibodies (anti-CdtB and anti-vinculin) levels are less than the indicated reference intervals.

A "supportive test" suggests that there is a greater clinical significance for IBS-D or IBS-M and that the IBS may be due to previous gastroenteritis or bacterial infection. A "not supportive" test does not exclude IBS-D or IBS-M, but may indicate that further studies are needed to rule out other causes for the patient's gastrointestinal symptoms and/or complaints.

The boxed portion of the above chart is representative of the 95% confidence interval of 2.80 ± 0.24 OD units for anti-CdtB or 1.68 ± 0.34 OD units for anti-vinculin which indicates the test result is "borderline" between a supported and not supported diagnosis. Results should be considered in the context of the overall clinical evaluation of this patient.

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 used for clinical purposes and should not be regarded as investigationa or for research.

Reference 1: Pimentel M, Morales W, Rezaie A, Marsh E, Lembo A, Mirocha J, et al. (2015) Development and Validation of a Biomarker for Diarrhea-Predominant Irritable Bowel Syndrome in Human Subjects. PLoS ONE 10(5): e0126438.
Reference 2: Rezaie, A., Park, S.C., Morales, W. et al. Assessment of Anti-vinculin and Anti-cytolethal Distending Toxin B Antibodies in Subtypes of Irritable Bowel Syndrome. Dig Dis Sci (2017) 62: 1480.
Reference 3: M. Schmulson, R. Balbuena, C. Corona de Law. Clinical experience with the use of anti-CdtB and anti-vinculin antibodies in patients with diarrhea in Mexico. Revista de Gastroenterología de México, Volume 81, Issue 4, October–December 2016, Pages 236-239.

Reviewing Physician

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