Understanding Your Result Report

IBSchek® SAMPLE RESULT REPORT
ANTI-CDTB AND ANTI-VINCLUDIN TEST

**Patient Demographics**

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

**Test Date Information**

- **Test Type:** ANTI-CDTB AND ANTI-VINCLUDIN TEST
- **Barcode:** IB5000
- **Physician Name:** Jane Doe
- **Physician Address:** 573 Longwood Avenue, Boston, MA 02205
- **Date Test Received:** 01/30/2021
- **Date Test Reported:** 01/31/2021

**Analyte Tested**

- **Anti-CdtB** (campylobacter jejuni)
- **Anti-Vinculin** (human protein)

**Optical Density (OD) Patient Values**

- **Anti-CdtB:** 3.10
- **Anti-Vinculin:** 0.00

**Reference Intervals**

- **Normal < 2.80 OD units**
- **Normal < 1.68 OD units**

**Result Interpretation**

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.

**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**

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 investigational or for research.

