Table 1. Studies Supporting RestorFlora™

Study	Subjects	Variables Studied	Outcome
Bacillus clausii			
Nista EC, Candelli M, Cremonini F, et al. Bacillus clausii therapy to reduce side-effects of anti-Helicobacter pylori treatment: randomized, double-blind, placebo-controlled trial. *Alimentary Pharmacology and Therapeutics*. 2004;20(10):1181-1188.	120 adults with *H. pylori*	effect of *Bacillus clausii* on incidence and severity of antibiotic-associated side-effects during anti-*H. pylori* therapy	*B. clausii* reduces the incidence of the most common side-effects related to anti-*H. pylori* antibiotic therapy
Marseglia GL, Tosca M, Cirillo I, et al. Efficacy of Bacillus clausii spores in the prevention of recurrent respiratory infections in children: a pilot study. *Therapeutics and Clinical Risk Management*. 2007;3(1):13-17. doi:10.2147/tcrm.2007.3.1.13.	80 children with recurrent respiratory infection	Activity and duration of respiratory infection, safety of *B. clausii*	*B. clausii* treatment is safe significantly effective in reducing the duration of RI in children with recurrent disease
Gabrielli M, Lauritano E, Scarpellini E. genes involved in immune response and inflammation, apoptosis and cell growth, cell differentiation, cell–cell signalling, cell adhesion, signal transcription and transduction. *The American Journal of Gastroenterology*. 2009;104:1327-1328.	40 adults	SIBO decontam-ination rate, tolerance of probiotic supplementation	Decontamination rate of SIBO using B. clausii is comparable to that observed with many antibiotics. B clausii is extremely safe and well tolerated
Ciprandi G, Tosca MA, Milanese M, Caligo G, Ricca V. Cytokines evaluation in nasal lavage of allergic children after Bacillus clausii administration: A pilot study. *Pediatric Allergy and Immunology*. 2004;15(2):148-151.	10 children	Levels of interleukins, (IFN)-c, (TGF)-b, and (TNF)-a	*B. clausii* may exert immuno-modulating activity by affecting cytokine pattern
Di Caro S, Tao H, Grillo A, et al. Bacillus clausii effect on gene expression pattern in small bowel mucosa using DNA microarray analysis. *European Journal of Gastroenterology & Hepatology*. 2005;17(9):951-960.	6 adults	modification of gene expression	*B. clausii* affects upregulation and downregulation of genes, mainly those which are involved with immune response and inflammation, apoptosis and cell growth, cell differentiation, cell signaling, cell adhesion, and signal transcription and transduction
Urdaci MC, Bressollier P, Pinchuk I. Bacillus clausii Probiotic Strains. *Journal of Clinical Gastroenterology*. 2004;38(Supplement 2).	Murine cells	Antimicrobial and immunomodulatory activities	*B. clausii* in their vegetative forms are active against *Staphylococcus aureus, Enterococcus faecium,* and *Clostridium difficile*

Bacillus subtilis			
Uyen NQ, Hong HA, Cutting SM. Enhanced immunisation and expression strategies using bacterial spores as heat-stable vaccine delivery vehicles. *Vaccine*. 2007;25(2):356-365.	Mice	Immune response, antigen expression	*Bacillus subtilis* elicits protective immune response when exposed to TTFC antigen of *Clostridium tetani*
Hong H, Khaneja R, Tam N. Bacillus subtilis isolated from the human gastrointestinal tract. *Research in Microbiology*. 2009;160:134-143.	6 human subjects dyspeptic symptoms	Presence and activity of *B. subtilis* within human GIT (antimicrobial activity)	Bacillus subtilis is naturally present in human GIT and should be considered a human gut commensal
Saccharomyces boulardii			
Czerucka D, Dahan S, Mograbi B, Rossi B, Rampal P. Saccharomyces boulardii Preserves the Barrier Function and Modulates the Signal Transduction Pathway Induced in Enteropathogenic Escherichia coli-Infected T84 Cells. *Infection and Immunity*. 2000;68(10):5998-6004.	human colon T84 cell line	disease activity, distribution of ZO-1, adhesion, transepithelial resistance, apoptosis of epithelial cells	*S. boulardii* reduces the negative consequences of enteropathogenic *E. coli* infection
Demirel G, Celik IH, Erdeve O, et al. Prophylactic Saccharomyces boulardii versus nystatin for the prevention of fungal colonization and invasive fungal infection in premature infants. *Eur J Pediatr*. 2013;172:1321-1326.	181 premature infants	fungal colonization and infection, sepsis, feeding tolerance	*S. boulardii* supplementation is as effective as nystatin in reducing fungal colonization, and more effective than nystatin in reducing invasive fungal infection