**Commonwealth Laboratories, Inc. Announces Launch of IBS*chek****™****,* a New, Simple Blood Test to Quickly and Reliably Diagnose Irritable Bowel Syndrome (IBS)**

*New Diagnostic Test for IBS Can Reduce Frustration, Time and Cost Associated with the Current Practice of Diagnosis by Exclusion Used for an Estimated 40 Million IBS Sufferers*

Salem, Massachusetts, May 14, 2015 -- [Commonwealth Laboratories, Inc.](http://hydrogenbreathtesting.com/) (“Commonwealth”) announced today the availability of [IBS*chek™*](http://www.ibschek.com/), a new blood test designed to help physicians quickly and reliably diagnose Irritable Bowel Syndrome (IBS). Within 24 hours of receiving the blood specimen, the test identifies the presence of two antibodies - anti-CdtB and anti-vinculin, which recent data have shown to be indicative of diarrhea-prominent IBS. These data, which will be presented during an oral session at Digestive Disease Week® 2015 in Washington, D.C., show that for the first time ever, researchers have identified an organic biomarker for the diagnosis of IBS. Prior to the introduction of IBS*chek™*, a diagnosis of IBS was typically made after excluding all other conditions. This often requires multiple costly diagnostic tests over an average of five years to rule out other conditions before coming to a confident diagnosis of IBS.

The study was also published in the peer-reviewed journal, *PLOS ONE*, on May 13, 2015. Please see the link to the manuscript “Development and Validation of a Biomarker for Diarrhea-Predominant Irritable Bowel Syndrome in Human Subjects” by Pimentel M, Morales W, Rezaie A, et al. here:

<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0126438>. IBS*chek*™ is supported by this statistically significant data from a 180 center, large-scale, randomized clinical trial of 2,681 (IBS n=2,375) patients, comparing those with IBS against patients with Inflammatory Bowel Disease (IBD) and Celiac Disease, as well as healthy controls.

“Data from this study validates our long-held suspicion that IBS is caused by infection, by way of confirming anti-vinculin and anti-CdtB as blood-based biomarkers that provide a differential diagnosis of IBS,” says Mark Pimentel, M.D., FRCPC, Director of the Gastrointestinal Motility Program and Laboratory at Cedars-Sinai. “This study suggests that IBS*chek*™ is an important new tool that allows healthcare providers to quickly and accurately diagnose IBS, one of the most challenging gastrointestinal disorders to diagnose.” Cedars-Sinai granted Commonwealth exclusive license rights to the intellectual property vital to the development of IBS*chek*™.

IBS is the most common gastrointestinal disorder in the U.S., affecting nearly 40 million Americans and approximately 15% of the world’s total population. It is more common in women than in men and the symptoms can be very difficult to diagnose. Until now, it has been unknown whether or not there is a natural cause of IBS. As a result, IBS patients typically consult with more than four healthcare providers before they are diagnosed with the disorder. In addition, up to 70% of people with IBS do not consult their healthcare provider regarding their symptoms, thinking their symptoms are not serious enough, or are caused by secondary factors such as diet, stress, anxiety or depression. This means that many patients are living with IBS without being properly diagnosed. IBS*chek™* is a simple enzyme-linked immunosorbent assay (ELISA) based test that aims to change this paradigm. The test can be conducted via standard blood draw in a healthcare provider’s office, with results reported within 24 hours of the patient’s blood specimen being received by Commonwealth for analysis.

“The launch of IBS*chek™* is an unprecedented step forward in the diagnosis of IBS. It is an exciting scientific breakthrough that can assist patients and healthcare providers alike in identifying the cause of the disease, as well as provide hope and relief to the millions of Americans who have endured years of frustration and suffering associated with their digestive discomfort” says Craig Strasnick, Chief Operating Officer at Commonwealth. IBS*chek™* uniquely addresses the needs of IBS patients with GI discomfort by either confirming an IBS diagnosis, or potentially eliminating it as a cause of symptoms. More information on IBS*chek™* can be found at [http://www.IBSchek.com](http://www.ibschek.com/).

If a patient tests positive for IBS with IBS*chek*™, it means there is a high degree of medical certainty that he or she has Diarrhea-predominant IBS and not another disease, such as IBD (specificity of 91.6%) or celiac disease. Although IBS*chek*™ is highly predictive of an IBS diagnosis, an inconclusive result with IBS*chek*™ may not mean that the patient definitively does not have IBS. An inconclusive IBS*chek*™ result simply may mean that 1) further investigation into the cause of symptoms may need to be conducted 2) the cause of the IBS is attributed to an alternate mechanism outside of the mechanism that IBS*chek™* is looking for specifically, or 3) the symptoms may be caused by a disease other than IBS. An inconclusive test may help the physician narrow down the differential diagnosis, helping them get one step closer to a determination as to the cause of symptoms.

Additional resources, including product images, an infographic and a video of how the test works, can be found in our [Digital Newsroom](http://firstlinemedia.com/mnr/ibs/).

**About IBS*chek™***

IBS*chek™* tests for the presence of antibodies that are created when intestinal microbes (called microbiota) are altered by acute gastroenteritis. It detects levels of an antibody to a toxin from gastroenteritis called CdtB (cytolethal distending toxin B), as well as vinculin, an antibody that forms against the body. While the test is more specific for anti-CdtB, the anti-vinculin component suggests that IBS may be an autoimmune disease. The two antibody levels are complimentary in further understanding IBS and together enable a differential diagnosis of IBS.

**About IBS**

Irritable Bowel Syndrome (IBS) is a gastrointestinal disorder in which symptoms are due to dysfunction of the gut. There are three different types of IBS, with an equal number of people in each category: IBS with constipation, IBS with diarrhea, and IBS with alternating constipation and diarrhea. IBS with constipation comes with stomach pain and discomfort, bloating, abnormally delayed or infrequent bowel movement, or lumpy/hard stool. IBS with diarrhea comes with stomach pain and discomfort, an urgent need to move your bowels, abnormally frequent bowel movements, or loose/watery stool.

IBS is the most common gastrointestinal disorder in the U.S., affecting approximately 40 million Americans, yet the exact cause is unknown. IBS affects about twice as many women as men and is most often found in people younger than age 45.

**About Commonwealth Laboratories, Inc.**

Headquartered in Salem, Massachusetts, Commonwealth Laboratories, Inc. is a state and federally licensed, FDA-registered independent diagnostic laboratory offering specialized, clinical hydrogen and methane breath gas analytics to aid in the diagnosis of Small Intestinal Bacterial Overgrowth and other malabsorption disorders.

Commonwealth has most recently developed IBS*chek™,* the only quick and reliable blood test to assist healthcare providers in the diagnosis of Irritable Bowel Syndrome (IBS). IBS*chek™* is based on the scientific findings of Mark Pimentel, MD, which showed that anti-vinculin and anti-CdtB are effective biomarkers for the diagnosis of IBS. The test utilizes a proprietary, ELISA-based blood test, providing results within 24 hours of sample receipt at Commonwealth. Its turnkey approach is office-friendly and assists in providing the healthcare provider with the objective data they need to make an informed diagnosis, while also providing validation for the symptoms and associated discomfort that patients have been experiencing for extensive periods of time.

For more information about IBS*chek*™, please call (877) IBS-CHEK (427-2435) or visit <http://www.IBSchek.com>. For information regarding any other services provided by Commonwealth, please call (800) 292-9019 or email [inquiries@commlabsinc.com](mailto:inquiries@commlabsinc.com).

**About Digestive Disease Week®**

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 16–19, 2015, at the Walter E. Washington Convention Center, Washington, DC. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at [www.ddw.org](http://www.ddw.org).

**About Cedars-Sinai**

Cedars-Sinai is internationally renowned for its diagnostic and treatment capabilities and its broad spectrum of programs and services, as well as advances in biomedical research and innovative medical education programs. For more than 20 years, Los Angeles-area residents have named Cedars-Sinai the "Most Preferred Hospital for All Health Needs" in National Research Corporation's annual Healthcare Market Guide survey. Cedars-Sinai Medical Group and Cedars-Sinai Health Associates both ranked among the top 10 physician groups in Southern California by Integrated Health Care Associates (IHA), a California leadership group of health plans,physician groups, and health systems.

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