Commonwealth Diagnostics International INC
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Commonwealth Diagnostics International Introduces Validated At-Home Collection Kit for IBS*chek*®

The Improved Sample Collection Method Expands Access to the Blood Test for Diagnosing Diarrhea-Predominant and Mixed-Type Irritable Bowel Syndrome

SALEM, MA February 1, 2020 - Commonwealth Diagnostics International (CDI), Inc., an international diagnostic service provider specializing in functional gastrointestinal disorders, recently announced the commercial re-launch of IBS*chek*®, the first clinically validated biomarker blood test for diarrhea-predominant and mixed-type Irritable Bowel Syndrome (IBS-D, IBS-M) in a new at-home capillary collection kit.

Today, CDI announced that it has successfully completed validation of a self-contained sample collection kit for the proprietary blood-based test. A provider looking to request IBS*chek* can now use the IBS*chek* Capillary Blood Collection Kit to quickly and painlessly collect a patient sample at the time of their appointment, or they can send the patient home with the test kit to complete the collection on their own. The kit doubles as the return-shipping box and includes a pre-paid return label. This innovative sample collection solution removes the inconvenience of arranging secondary blood-draw appointments and improves patient experience without sacrificing clinical integrity or validity of the results.

Manufactured by CDI at its ISO 13485 certified facility, the newly developed capillary collection kit has been validated by CDI's independent, CLIA-certified laboratory and has been registered with the FDA. The validation study compared the IBS*chek* results from capillary EDTA whole blood (3mL) collected by a professional phlebotomist to the results obtained when participants collected their own capillary EDTA whole blood (500µL) using the IBS*chek* Capillary Blood Collection Kit components and included instructions for use. The study found no deviations between samples collected at home and samples collected by a professional phlebotomist, and the analytes in at-home collected samples were able to produce a 100% match-up to professionally drawn samples with a mean confidence interval of 0.24. "We are excited to launch this product to give doctors and patients an easy, more streamlined approach to diagnosing IBS with the ability to quickly test in-office or the comfort of the patient's home with a simple finger stick." says Craig Strasnick, President and CEO from CDI.

The basic at-home collection kit has everything needed to allow patients or providers to safely collect and ship a capillary blood sample conveniently by incorporating the most advanced and intuitive capillary collection technology into CDI's existing patient-centric sample collection and return-shipping processes. This product advancement will lower costs associated with the test and shorten time to results by eliminating the need for additional sample collection appointments. More information about the kits, including how to order, can be found on CDI's website at www.CommDx.com, or contact our customer service department at 888-258-5966.

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Published Clinical Data Validating IBS*chek* for Diagnosing IBS-D and IBS-M

"Development and Validation of a Biomarker for Diarrhea-Predominant Irritable Bowel Syndrome in Human Subjects" Mark Pimentel, Walter Morales, Ali Rezaie, et al. *PLoS One*. 2015; 10:e0126438.

"Assessment of Anti-vinculin and Anti-cytolethal Distending Toxin B Antibodies in Subtypes of Irritable Bowel Syndrome." Rezaie A, Park SC, Morales W et al. *Dig Dis Sci.* 2017 Jun; 62(6):1480-1485.

"Clinical experience with the use of anti-CdtB and anti-vinculin antibodies in patients with diarrhea in Mexico." Schmulson M, Balbuena R, Corona de Law C. *Rev Gastroenterol Mex.* 2016 Oct - Dec;81(4):236-239.

"The Utility of Measuring Anti-Cytolethal Distending Toxin B and Anti-Vinculin Antibodies in a Tertiary Care Motility Practice: A Free-Range Experience." Pourmorady J, Rezaie A, Pimentel M, et al. Gastroenterology. 2016;4 (Suppl1): S-230.