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Biophor Diagnostics, Inc. Announces Seventh FDA 510(k) Clearance, Completing Panel of Rapid, Homogeneous Screening Tests for Drugs of Abuse in Oral Fluid

Clearances Support the Versatility of Biophor's RapidFRET® IVD Platform Technology for Saliva Samples

REDWOOD CITY, Calif., Oct. 19, 2015 /PRNewswire/ -- Biophor Diagnostics, Inc. (<http://www.biophor.com> (<http://www.biophor.com/>)) announces that it has received FDA 510(k) clearance for sale and distribution of its seventh oral fluid screening assay based on the RapidFRET® IVD Platform technology. This clearance completes the company's flagship panel for drugs of abuse screening in oral fluid.

Biophor is a pioneer in the oral fluid diagnostics industry developing immunoassays for undiluted or 'neat' oral fluid specimens obtained with the RapidEASE® Oral Fluid Collector. Oral fluid is a preferred sample type as it is easy to collect, hard to adulterate, and does not have the privacy issues associated with urine samples. Biophor will leverage the globally accelerating growth of oral fluid diagnostics (7.7% CAGR) relative to urine (4.6% CAGR) and other matrices to capture a significant portion of the \$2.8B worldwide drugs of abuse testing market.

"Oral fluid specimens collected with absorbent pads placed into diluents suffer from irreversible non-specific adsorption of analytes, inaccurate sample dilution and complicated processing at the lab," said Dr. Nathaniel Butlin, Vice-President of Biophor. "Undiluted oral fluid is the best possible sample for accurate analysis, and the RapidFRET IVD platform evolved from that fundamental premise."

The most recently cleared test is for d-methamphetamine at a 50 ng/mL cutoff and completes the panel, which includes the most widely needed tests for d-amphetamine (50 ng/mL cutoff), cocaine and benzoylecgonine (20 ng/mL cutoff), opiates (40 ng/mL cutoff), PCP (10 ng/mL cutoff), THC (4 ng/mL) and MDMA (50 ng/mL).

The RapidFRET IVD Platform is a complete oral fluid screening solution that includes a proprietary collection device, rapid, homogeneous reagents, and an instrument with full walk-away automation. The system fundamentally raises the bar for laboratory-based oral fluid screening with simplified sample handling, sample ID, reagent lot, and liquid handling traceability, rapid and continuous data generation, and the most accurate oral fluid sampling technique available.

"We are extremely pleased to reach this significant milestone for the company and for oral fluid drug testing. Biophor's RapidFRET IVD Platform raises the bar for accuracy and efficiency of in vitro diagnostic solutions and is a versatile system for continued IVD development," said Dr. Todd Corneillie, President of Biophor.

Biophor's menu of screening assays is being expanded to include pain-management and other abused prescription drugs, leveraging previously identified antibodies and critical raw materials. Biophor has also demonstrated technical feasibility for other sample matrices such as urine and hair extracts with pipeline validation planned for serum and plasma.

The company is in the process of seeking partnerships to bring these products to the US and global markets. Biophor will be attending the SOFT 2015 conference and interested parties are encouraged to visit the Biophor booth in Atlanta. Further information on Biophor's clearances can be found on the FDA's website (www.fda.gov) under the following 510(k) numbers: k141748 (amphetamine), k142129 (cocaine), k142293 (methamphetamine), K133642 (opiates), k122703 (phencyclidine), k132096 (THC), and k133047 (MDMA).

About Biophor Diagnostics, Inc.

Biophor is a privately held company located in Redwood City, California that is a leader in developing novel IVD immunoassay systems. Biophor has developed the RapidFRET® IVD platform technology as a superior alternative to existing homogeneous immunoassay techniques. The platform includes the RapidFRET Integrated Workstation, a custom analyzer with rapid reagents and full walk-away automation, the RapidEASE® Oral Fluid sample collector and a suite of products for oral fluid and hair extract screening. Although the flagship products are initially focused on oral fluid screening for drugs of abuse, the platform is widely applicable to diagnostics in urine, serum, plasma and extracted samples such as hair. Biophor is evaluating strategic alliances to facilitate rapid market penetration of the RapidFRET screening products within the United States and worldwide.

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