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Catachem Announces FDA Approval of the Direct Bilirubin (DBILI) In-Vitro

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Catachem Announces FDA Approval of the Direct Bilirubin (DBILI) In-Vitro Diagnostic (IVD) Chemistry Reagent Kit

Bridgeport, Connecticut, USA (April 13, 1989).... Catachem, Inc. (Private) announced today that it has received 510k clearance from the United States Food and Drug Administration (FDA) for the Direct Bilirubin (DBILI) in vitro diagnostic chemistry reagent kit.

Measurements of Direct Bilirubin (DBILI) in blood are used for diagnosing obstructive jaundice and hepatitis, as well as to monitor the causes and treatment. Bilirubin is a brownish yellow substance found in bile. Bilirubin is produced when the liver breaks down hemoglobin, the oxygen-carrying substance in red blood cells. Bilirubin is then removed from the body through the stool (feces) and gives stool its normal brown color. Bilirubin circulates in the bloodstream in two forms: Indirect (or unconjugated) bilirubin. This form of bilirubin does not dissolve in water (it is insoluble). Indirect bilirubin travels through the bloodstream to the liver, where it is changed into a soluble form. Direct (or conjugated) bilirubin. After indirect bilirubin has been changed by the liver into a form that dissolves in water (soluble), it is called direct or conjugated bilirubin. Total bilirubin and direct bilirubin levels are measured directly in the blood, whereas indirect bilirubin levels are derived from the total and direct bilirubin measurements. The most obvious symptom of high bilirubin levels is jaundice, a condition in which the skin and whites of the eyes appear yellow. Jaundice is caused by the buildup of bilirubin in the blood and skin from liver disease (hepatitis), blood disorders (haemolytic anemia), or blockage of the tubes (bile ducts) that allow bile to pass from the liver to the small intestine. Excessive buildup of bilirubin in a newborn baby sometimes causes brain damage and even death. Therefore, some babies who develop jaundice may be treated with special lights or a blood transfusion to reduce their bilirubin levels. This test is done on a blood sample taken from a vein. In a newborn baby, the blood sample is usually taken from the heel (heel stick). Serum is mixed with diazotized sulfanilic acid to form the azo-bilirubin complex. The increase in absorbance is monitored at 550 nm. DBILI is a two reagent chemistry and kits for R2 are available in one size, reagents for R1 and reagents for R2 are available separately. Reagents are packaged in small glass bottles. Calibrator and controls are available separately. DBILI R2 Kit C304-0A 530 tests, DBILI Reagents: DBILI R1 C304-03 1x500 ML, DBILI R2a C304-01 6x25 ML, DBILI R2b C315-05 6x1.5 ML, DBILI R1 C302-01, 4x500 ML, DBILI R2a C302-03 12x8.1 ML, DBILI R2b C302-04 5x250 ML.

About Catachem, Inc.

Founded in 1984 Catachem has a rich 20 year history in clinical chemistry as a manufacturer and distributor of in-vitro chemistry products and services for assays in human, veterinary and environmental laboratories.

Catachem chemists helped develop many of the automated diagnostic chemistries widely in use today. Catachem created the **DiscretePak™** and **VetSpec™** line of reagents for human diagnostic and veterinary diagnostic automated analyzers. Catachem offers FDA approved (510K) chemistries (liquid and dry) including enzymatic chemistries developed in conjunction with IFCC and CDC. Catachem has more than 500 applications for all types of analyzers including the Roche™ Hitachi™ series, Olympus™ AU Series™, RA Series™, Opera™ and DAX™, Bayer™ Advia™, Synchron™, Beckman™, Abbott™ and many other analyzers. Corporate headquarters, research, custom formulation laboratories, and manufacturing are located in Bridgeport, Connecticut. Catachem supplies leading laboratories and equipment manufacturers from distributors around the world.

Forward-looking statements in this release are made pursuant to the "safe harbor" provision of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements involve risks and uncertainties including, but not limited to, the results of research and development efforts, the effect of regulation by the United States Food and Drug Administration and other agencies, the impact of competitive products, product development commercialization and technological difficulties, and other risks detailed in the Company's periodic reports filed with the Securities and Exchange Commission.

Keywords: Catachem, Chemistry, Reagents, In-Vitro Diagnostics, IVD, Direct Bilirubin, DBILI, haemolytic anemia, hepatitis

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Catachem chemistries include: 5'-Nucleotidase (5NT), Adenosine Deaminase (ADA), Alanine Aminotransferase (ALT), Albumin BCG (ALB), α -L-Fucosidase (AFU), Alkaline Phosphatase (ALP), Ammonia (NH), Amylase (AMY), Aspartate Aminotransferase (ALP), ²-Hydroxybutyrate (BHBA), Bicarbonate (HC03), Bile Acids (BA), Bilirubin, Direct with Blank (DBILI), Bilirubin, Total with Blank (TBILI), Bilirubin, Total (TBILI), Blood Urea Nitrogen (BUN), Bromide (BR), CO₂ [340] (CO₂), CO₂ [380] (CO₂), CO₂ [single reagent] (CO₂), Ca⁺⁺⁺ Arsenazo [650NM] (CA3), Chloride [340 NM] (CL), Cholesterol (CH), Creatine Kinase (CK), Creatinine (CREAT), Fructosamine [millimole method] (FR), Fructosamine, Glycated Serum Protein [enzymatic] (FR), Gamma-Glutamyl Transpeptidase (GGT), Glucose Hexokinase (GLU), Glycated Hemoglobin (HbA1c), High Density Lipoproteins, Dextran Sulfate (HDL), Inorganic Phosphorus (IP), Lactate Dehydrogenase (LD), Lipase (LIP), Lithium [enzymatic] (LI), Magnesium (MG), N-Acetyl- β -D-glucosaminidase (NAG), Potassium [enzymatic] (K), Plasma Free Hemoglobin (PFH), Pre-albumin (TBPA), Sodium [enzymatic] (NA), Sorbitol Dehydrogenase (SDH), Thiopurine methyltransferase (TPMT), Total Bile Acids (TBA), Total Iron (TI), Total Protein (TP), Triglycerides (TRIG), UIBC and TIBC (UIBC), Uric Acid (UA), Vitamin B6 (V6B), Multipoint Calibrator Catacal, Catatrol Level 1 Catatrol Level 2, Bile Acids Control, Bile Acids Calibrator, BHBA Calibrator, BHBA Control Level 1, BHBA Control Level 2; Bromide Calibrator, BR Control Level 1, BR Control Level 2; Fructosamine Calibrator, FR Control Level 1, FR Control Level 2, SDH Control Level 1, SDH Control Level 2. Call +1 (203) 335-9277 or Write Catachem@aol.com.

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