

# DIAZYME OFFERINGS

Parameters for Multiple Platform Types

Calibrators ● Controls ● Bulk Reagent Packaging

## POINT OF CARE (POC) SYSTEMS



**CUBE-A\*\***  
• PCT\*\*

\*\*USA: For Research Use Only



**SMART Assay System**

- Cystatin C
- Homocysteine
- hsCRP
- Wide Range CRP\*\*
- HbA1c
- GSP
- PCT\*

\*USA: For Research Use Only

## INSTRUMENT SPECIFIC PACKAGING

**Beckman AU**



- Enzymatic Homocysteine
- Cystatin C
- Direct Enzymatic HbA1c
- Enzymatic Creatinine
- Lp(a)
- HDL
- LDL
- TBA Cycling
- CO<sub>2</sub>
- Lipase
- GSP
- PCT\*

**Beckman Synchron**



- Enzymatic Homocysteine
- Cystatin C
- Direct Enzymatic HbA1c
- Enzymatic Lithium
- Lp(a)
- HDL
- LDL
- TBA Cycling
- CO<sub>2</sub>
- PCT\*

**Siemens Dimension  
EXL, RXL and Xpand**



- Enzymatic Homocysteine
- Direct Enzymatic HbA1c
- Cystatin C
- HDL
- LDL
- PCT\*

\*USA: For Research Use Only

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## PRODUCT OFFERINGS

# 2016

**INNOVATIONS IN CLINICAL DIAGNOSTICS**

ANEMIA MARKERS	Method	Regulatory Status
Ferritin Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ 510(k) Cleared
CANCER MARKERS	Method	Regulatory Status
α-Fetoprotein (AFP) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ USA: For Research Use Only
Carcinoembryonic Antigen (CEA) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ USA: For Research Use Only
Free Light Chain Kappa Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	USA: For Research Use Only
Free Light Chain Lambda Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	USA: For Research Use Only
Pepsinogen I (PG I) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	USA: For Research Use Only
Pepsinogen II (PG II) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	USA: For Research Use Only
Prostate Specific Antigen (PSA) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	USA: For Research Use Only
CARDIOVASCULAR MARKERS	Method	Regulatory Status
Apolipoprotein A-1 (APO A-1) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ 510(k) Cleared
Apolipoprotein B (APO B) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ 510(k) Cleared
Cardiac Troponin I Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ USA: For Research Use Only
Digoxin Assay	(Dual Vial Liquid Stable) (Enzyme Immunoassay)	USA: For Research Use Only
HDL-Cholesterol Assay	(Dual Vial Liquid Stable) (PVS/PEGME Coupled)	☑ 510(k) Cleared
Heart-Type Fatty Acid-Binding Protein (H-FABP) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ USA: For Research Use Only
Homocysteine Assay	(Three Vial Liquid Stable) (Enzyme Cycling)	☑ 510(k) Cleared Health Canada Registered
Homocysteine Assay	(Dual Vial Liquid Stable) (Enzyme Cycling)	☑ 510(k) Cleared Health Canada Registered
hs-Troponin I Assay	(Dual Vial Liquid Stable) (Immunochemiluminescent)	USA: For Research Use Only
LDL-Cholesterol Assay	(Dual Vial Liquid Stable) (PVS/PEGME Coupled)	☑ 510(k) Cleared
Lipoprotein (a) Lp(a) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ 510(k) Cleared Health Canada Registered
Lp-PLA <sub>2</sub> Activity Assay	(Three Vial Liquid Stable) (Enzymatic)	USA: For Research Use Only
Myoglobin Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ 510(k) Cleared
COAGULATION MARKERS	Method	Regulatory Status
D-Dimer Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ 510(k) Cleared
Fibrinogen Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	USA: For Research Use Only
DIABETIC MARKERS	Method	Regulatory Status
Adiponectin Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	USA: For Research Use Only
Albumin (BCG) Assay	(Liquid Stable) (Bromocresol Green)	☑ 510(k) Cleared
Direct Enzymatic HbA1c Assay	(Liquid Stable) (Single Channel)	☑ 510(k) Cleared Health Canada Registered
Glycated Serum Protein (GSP) Assay	(Enzymatic) (Dual Vial Liquid Stable)	☑ 510(k) Cleared Health Canada Registered
Insulin Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ 510(k) Exempt
Retinol Binding Protein (RBP) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ 510(k) Exempt

ELECTROLYTE MARKERS	Method	Regulatory Status
Carbon Dioxide (CO <sub>2</sub> ) Assay	(Single Vial Liquid Stable) (Enzyme Cycling 405nm)	☑ 510(k) Cleared
Lithium Assay	(Dual Vial Liquid Stable) (Enzymatic)	☑ 510(k) Cleared Health Canada Registered
Potassium Assay	(Dual Vial Liquid Stable) (Enzymatic)	☑ 510(k) Cleared
Sodium Assay	(Dual Vial Liquid Stable) (Enzymatic)	☑ 510(k) Cleared
INFLAMMATORY MARKERS	Method	Regulatory Status
hsCRP Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ 510(k) Cleared
Myeloperoxidase (MPO) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ USA: For Research Use Only
Wide Range CRP	(Dual Vial Liquid Stable) (Immunoturbidimetric)	USA: For Research Use Only
LIVER MARKERS	Method	Regulatory Status
5'-Nucleotidase (5'NT) Assay	(Dual Vial Liquid Stable) (Enzymatic)	☑ 510(k) Exempt Health Canada Registered
α-L-Fucosidase (AFU) Assay	(Single Vial Liquid Stable) (Enzymatic)	☑ USA: For Research Use Only
Adenosine Deaminase (ADA) Assay	(Dual Vial Liquid Stable) (Enzymatic)	☑ USA: For Research Use Only
Cholylglycine (CG) Assay	(Dual Vial Liquid Stable) (Enzymatic)	USA: For Research Use Only
Direct Bilirubin Assay	(Dual Vial Liquid Stable) (Vanadate)	☑ 510(k) Cleared
Total Bilirubin Assay	(Dual Vial Liquid Stable) (Vanadate)	☑ 510(k) Cleared
Total Bile Acids (TBA) Assay	(Dual Vial Liquid Stable) (Enzyme Cycling)	☑ 510(k) Cleared Health Canada Registered
Total Bile Acids (TBA) Assay	(Dual Vial Liquid Stable and Powder) (NBT Method)	USA: For Research Use Only
RENAL AND PANCREATIC MARKERS	Method	Regulatory Status
Creatinine Assay	(Dual Vial Liquid Stable) (Enzymatic)	☑ 510(k) Cleared
Cystatin C Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ 510(k) Cleared
Lipase Assay	(Dual Vial Liquid Stable) (Methyl-Resorufin)	☑ 510(k) Exempt
N-Acetyl-β-D-Glucosaminidase (NAG) Assay	(Three Vial Liquid Stable) (Colorimetric)	☑ USA: For Research Use Only
Neutrophil Gelatinase-Associated Lipocalin (NGAL) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	USA: For Research Use Only
SEPSIS MARKERS	Method	Regulatory Status
Procalcitonin (PCT) Assay	(Dual Vial Liquid Stable) (Immunoturbidimetric)	☑ USA: For Research Use Only
VITAMIN MARKERS	Method	Regulatory Status
25-Hydroxy Vitamin D EIA Test Kit	(Three Vial Liquid Stable) (ELISA Format)	☑ 510(k) Cleared Health Canada Registered
25-OH Vitamin D Assay for Chemistry Analyzers	(Three Vial Liquid Stable) (Enzyme Immunoassay)	☑ 510(k) Cleared Health Canada Registered
Folate Assay	(Four Vial Liquid Stable) (Enzyme Immunoassay)	USA: For Research Use Only
Vitamin B12 Assay	(Four Vial Liquid Stable) (Enzyme Immunoassay)	☑ USA: For Research Use Only
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