



PRODUCT LIST



Innovations In Clinical Diagnostics

ABOUT DIAZYME

Diazyme Laboratories, Inc. is located in Poway, California. Diazyme uses its proprietary enzyme and immunoassay technologies to develop diagnostic reagents which can be used on most automated chemistry analyzers in user-friendly formats. Diazyme is a cGMP and ISO 13485 certified medical device manufacturer. Diazyme's products include test kits for diagnosis of cardiovascular disease, liver disease, cancer markers, renal disease, diabetes and electrolytes.

MISSION STATEMENT

Our mission is to improve the quality of healthcare by providing innovative products in clinical diagnostics.

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* USA: For Research Use Only. Not For Use In Diagnostic Procedures.

DZ169A Human Kappa Free Light Chain Assay 510(k) Cleared; EU: **CE IVD**; Health Canada Registered

Catalog No.	Description	Format
DZ169A-K USA & Canada Only	Human Kappa Free Light Chain (liquid stable)	R1: 1 x 22mL R2: 1 x 7 mL Cal: 5 x 1.5 mL (Calibrator Included)
DZ169A-KY1 Export Only	Human Kappa Free Light Chain (liquid stable)	R1: 1 x 22 mL R2: 1 x 7 mL Cal: 5 x 1.5 mL vial (Calibrator Included)
DZ169A-CON	Human Kappa/Lambda Free Light Chain Control Set (liquid stable)	Con: 2 x 3 mL vial

DZ170A Human Lambda Free Light Chain Assay 510(k) Cleared; EU: **CE IVD**; Health Canada Registered

Catalog No.	Description	Format
DZ170A-KY1	Human Lambda Free Light Chain Assay (liquid stable)	R1: 1 x 22 mL R2: 1 x 7 mL Cal: 5 x 1.5 mL vial (Calibrator Included)
DZ169A-CON	Human Kappa/Lambda Free Light Chain Control Set (liquid stable)	Con: 2 x 3 mL

DZ863A Carcinoembryonic Antigen Assay EU: **CE IVD** *

Available In Bulk Packaging Format Only - Cal/Con Compatible Material Is Also Available (Please Contact The Diazyme Sales Department For More Information)

Catalog No.	Description	Format
DZ863A-R1L	Carcinoembryonic Antigen Assay, Bulk Reagent 1	R1: 800 mL
DZ863A-R2L	Carcinoembryonic Antigen Assay, Bulk Reagent 2	R2: 200 mL

DZ869A Alpha-Fetoprotein Assay EU: **CE IVD** *

Available In Bulk Packaging Format Only - Cal/Con Compatible Material Is Also Available (Please Contact The Diazyme Sales Department For More Information)

Catalog No.	Description	Format
DZ869A-R1L	Alpha-Fetoprotein Assay, Bulk Reagent 1	R1: 800 mL
DZ869A-R2L	Alpha-Fetoprotein Assay, Bulk Reagent 2	R2: 200 mL

CARDIOVASCULAR MARKERS

DZ128A LDL-Cholesterol Assay 510(k) Cleared; EU:

Catalog No.	Description	Format
DZ128A-KY1	LDL-Cholesterol Assay (liquid stable)	R1: 5 x 56 mL R2: 2 x 50 mL
DZ130A-CAL	HDL-LDL Cholesterol Calibrator (lyophilized)	Cal: 1 x 1 mL vial
DZ248A-CON	Multi-Analyte Lipid Control Set (lyophilized)	Con: 3 x 3 mL vial

DZ129A HDL-Cholesterol Assay 510(k) Cleared; EU:

Catalog No.	Description	Format
DZ129A-KY1	HDL-Cholesterol Assay (liquid stable)	R1: 5 x 56 mL R2: 2 x 50 mL
DZ130A-CAL	HDL-LDL Cholesterol Calibrator Set (lyophilized)	Cal: 1 x 1 mL vial
DZ248A-CON	Multi-Analyte Lipid Control Set (lyophilized)	Con: 3 x 3 mL vial

DZ131B Lipoprotein (a) Assay 510(k) Cleared; EU: Health Canada Registered

Catalog No.	Description	Format
DZ131B-KY1	Lipoprotein (a) (liquid stable)	R1: 1 x 60 mL R2: 1 x 20 mL
DZ131B-CAL	Lipoprotein (a) Calibrator Set (liquid stable)	Cal: 5 x 1 mL vial
DZ131B-CON	Lipoprotein (a) Control Set (liquid stable)	Con: 2 x 1 mL vial

DZ141A Apolipoprotein A-1 Assay 510(k) Cleared; EU: Health Canada Registered

Catalog No.	Description	Format
DZ141A-K	Apolipoprotein A-1 Assay (liquid stable)	R1: 1 x 26 mL R2: 1 x 10 mL
DZ141A-CAL	Apolipoprotein A-1/B Calibrator (lyophilized)	Cal: 1 x 1 mL vial
DZ248A-CON	Multi-Analyte Lipid Control Set (lyophilized)	Con: 3 x 3 mL vial

DZ142A Apolipoprotein B Assay 510(k) Cleared; EU: **CE** **IVD**

Catalog No.	Description	Format
DZ142A-K	Apolipoprotein B Assay (liquid stable)	R1: 1 x 26 mL R2: 1 x 10 mL
DZ141A-CAL	Apolipoprotein A-1/B Calibrator (lyophilized)	Cal: 1 x 1 mL vial
DZ248A-CON	Multi-Analyte Lipid Control Set (lyophilized)	Con: 3 x 3 mL vial

DZ145A Cardiac Troponin I Assay EU: **CE** **IVD** *

Catalog No.	Description	Format
DZ145A-K	Cardiac Troponin I Assay (liquid stable)	R1: 1 x 40 mL R2: 1 x 10 mL
DZ145A-CAL	Cardiac Troponin I Calibrator (liquid stable)	Cal: 6 x 1 mL vial
DZ145A-CON	Cardiac Troponin I Controls (liquid stable)	Con: 2 x 1 mL vial

DZ147A Myoglobin Assay 510(k) Cleared; EU: **CE** **IVD**

Available In Bulk Packaging Format Only - Cal/Con Compatible Material Is Also Available (Please Contact The Diazyme Sales Department For More Information)

Catalog No.	Description	Format
DZ147A-R1L	Myoglobin Assay, Bulk Reagent 1	R1: 783 mL
DZ147A-R2L	Myoglobin Assay, Bulk Reagent 2	R2: 217 mL

DZ565A DZ-Lite OxPL Lipoprotein Assay 510(k) Exempt

Catalog No.	Description	Format
DZ565A-CLIA	DZ-Lite OxPL Lipoprotein Assay (Oxidized Phospholipids on apo B-100)	Nano magnetic microbeads: 1 x 2.5 mL ABEI* Label: 1 x 12.0 mL Sample Diluent: 1 x 15.0 mL Cal Low/High: 2 x 1 mL Con Low/High: 2 x 1 mL
DZ565A-CON	DZ-Lite OxPL Lipoprotein Control Set	Con Low/High: 2 x 1 mL
DZ565A-WASH	OxPL Lipoprotein Wash Concentrate	Wash: 1 x 1000 mL

DZ566A Diazyme OxLDL Turbidimetric Assay 510(k) Exempt
Coming Soon

Catalog No.	Description	Format
DZ566A-KY1	Diazyme OxLDL Turbidimetric Assay (liquid stable)	R1: 1 x 44 mL R2: 1 x 14 mL
DZ566A-CAL	Diazyme OxLDL Turbidimetric Calibrator Set (lyophilized)	Cal: 5 x 0.5 mL vial
DZ566A-CON	Diazyme OxLDL Turbidimetric Control Set (lyophilized)	Con: 2 x 1 mL vial

DZ568A Homocysteine Enzymatic Assay 510(k) Cleared; EU:  IVD; Health Canada Registered

Catalog No.	Description	Format
DZ568A-K03	Homocysteine Enzymatic Assay (liquid stable)	R1: 1 x 25.5 mL R2: 1 x 5.8 mL R3: 1 x 4.8 mL
DZ568A-CA5	Homocysteine Enzymatic 5 Point Calibrator Set (liquid stable)	Cal: 5 x 3 mL vial
DZ568CAL	Homocysteine Enzymatic Assay Auto-dilution Calibrator (liquid stable)	Cal: 2 x 3 mL vial L1: 50 µmol/L
DZ568A-CON	Homocysteine Enzymatic Assay Control Set (liquid stable)	Con: 4 x 3 mL vial

DZ568B Homocysteine 2 Reagent Enzymatic Assay 510(k) Cleared; EU:  IVD; Health Canada Registered

Catalog No.	Description	Format
DZ568B-BY1	Homocysteine 2 Reagent Enzymatic Assay (liquid stable)	R1: 1 x 52 mL R2: 1 x 15 mL
DZ568B-BY2	Homocysteine 2 Reagent Enzymatic Assay (liquid stable)	R1: 2 x 52 mL R2: 2 x 15 mL
DZ568A-CA5	Homocysteine Enzymatic Assay 5 Point Calibrator Set (liquid stable)	Cal: 5 x 3 mL vial
DZ568A-CON	Homocysteine Enzymatic Assay Control Set (liquid stable)	Con: 4 x 3 mL vial

CARDIOVASCULAR MARKERS (Continued)

DZ785A Heart-Type Fatty Acid-Binding Protein EU: *

(H-FABP) Assay

Available In Bulk Packaging Format Only - Cal/Con Compatible Material Is Also Available
(Please Contact The Diazyme Sales Department For More Information)

Catalog No.	Description	Format
DZ785A-R1L	Heart-Type Fatty Acid-Binding Protein (H-FABP) Assay, Bulk Reagent 1	R1: 800 mL
DZ785A-R2L	Heart-Type Fatty Acid-Binding Protein (H-FABP) Assay, Bulk Reagent 2	R2: 200 mL

10-0148 PLAC[®] Test for Lp-PLA₂ Activity 510(k) Cleared; EU:

Catalog No.	Description	Format
10-0148	PLAC [®] Test for Lp-PLA ₂ Activity (liquid stable)	R1: 1 x 36 mL R2: 1 x 9 mL
100148B-CAL	Lp-PLA ₂ Activity Test Calibrators (lyophilized)	Cal: 5 x 1 mL
100148B-CON	Lp-PLA ₂ Activity Test Controls (lyophilized)	Con: 2 x 2 mL

COAGULATION

DZ179A D-Dimer Assay 510(k) Cleared; EU:

Catalog No.	Description	Format
DZ179A-K	D-Dimer Assay (liquid stable)	R1: 1 x 20 mL R2: 1 x 8 mL
DZ179A-CAL	D-Dimer Calibrator Set (lyophilized)	Cal: 5 x 1 mL vial
DZ179A-CON	D-Dimer Control Set (lyophilized)	Con: 2 x 1 mL vial

DZ768A Fibrinogen Assay 510(k) Cleared

Catalog No.	Description	Format
DZ768A-K	Fibrinogen Assay (liquid stable)	R1: 1 x 48 mL R2: 1 x 15 mL
DZ768A-CAL	Fibrinogen Assay Calibrator Set (lyophilized)	Cal: 3 x 1 mL vial
DZ768A-CON	Fibrinogen Assay Control Set (lyophilized)	Con: 2 x 1 mL vial

DZ112B Glycated Serum Protein Assay 510(k) Cleared; EU: **CE** **IVD**;
Health Canada Registered

Catalog No.	Description	Format
DZ112B-KY1	Glycated Serum Protein Assay (liquid stable)	R1: 1 x 60 mL R2: 1 x 17 mL
DZ112B-CAL	Glycated Serum Protein Calibrator Set (lyophilized)	Cal: 2 x 1 mL vial
DZ112B-CON	Glycated Serum Protein Control Set (lyophilized)	Con: 2 x 1 mL vial

DZ152A 1,5-Anhydroglucitol (1,5-AG) Assay 510(k) Cleared

Catalog No.	Description	Format
DZ152A-KY1	1,5-Anhydroglucitol (1,5-AG) Assay (liquid stable)	R1: 1 x 22 mL R2: 1 x 8 mL
DZ152A-CAL	1,5-Anhydroglucitol (1,5-AG) Calibrator Set (liquid stable)	Cal: 1 x 1 mL vial
DZ152A-CON	1,5-Anhydroglucitol (1,5-AG) Control Set (liquid stable)	Con High: 1 x 1 mL vial Con Low: 1 x 1 mL vial

DZ168A Direct Enzymatic HbA1c Assay 510(k) Cleared; EU: **CE** **IVD**;
Health Canada Registered

Catalog No.	Description	Format
DZ168A-K	Direct Enzymatic HbA1c Assay (liquid stable)	Lysis Buffer: 1 x 30 mL R1a: 1 x 16.8 mL R1b: 1 x 7.2 mL R2: 1 x 10 mL
DZ168A-CAL	Direct Enzymatic HbA1c Calibrator Set (lyophilized)	Cal: 2 x 0.5 mL vial
DZ168A-CON	Direct Enzymatic HbA1c Control Set (lyophilized)	Con: 2 x 0.5 mL vial

DIABETIC MARKERS (Continued)**DZ168C Direct HbA1c Assay (Enzymatic, On-Board Lysis)** 510(k) Cleared; EU: **CE** **IVD**; Health Canada Registered

Catalog No.	Description	Format
DZ168C-KY1	Direct HbA1c Assay (Enzymatic, On-Board Lysis) (liquid stable)	Lysis Buffer: 1 x 35 mL R1: 1 x 20.5 mL R2: 1 x 10 mL
DZ168C-CAL	Direct HbA1c Assay Calibrator Set (lyophilized)	Cal: 2 x 0.5 mL vial
DZ168C-CON	Direct HbA1c Assay Control Set (lyophilized)	Con: 2 x 0.5 mL vial

OTHER**DZ153A Beta-Hydroxybutyrate Assay** 510(k) Exempt; EU: **CE** **IVD**

Catalog No.	Description	Format
DZ153A-KY1	Beta-Hydroxybutyrate Assay (liquid stable)	R1: 1 x 24 mL R2: 1 x 7 mL
DZ153A-CAL	Beta-Hydroxybutyrate Calibrator (liquid stable)	Cal: 1 x 1 mL vial
DZ153A-CON	Beta-Hydroxybutyrate Controls (liquid stable)	Con: 2 x 3 mL vial
DZ153A-LIN	BHB High Level Control	Lin: 1 x 3 mL vial

DZ187A Retinol Binding Protein Assay 510(k) Exempt; EU: **CE** **IVD**

*Available In Bulk Packaging Format Only - Cal/Con Compatible Material Is Also Available
(Please Contact The Diazyme Sales Department For More Information)*

Catalog No.	Description	Format
DZ187A-R1L	Retinol Binding Protein Assay, Bulk Reagent 1	R1: 750 mL
DZ187A-R2L	Retinol Binding Protein Assay, Bulk Reagent 2	R2: 250 mL

ELECTROLYTE MARKERS

DZ113C Enzymatic Potassium Assay 510(k) Cleared; EU:

Catalog No.	Description	Format
DZ113C-K01	Enzymatic Potassium Assay (liquid stable)	R1: 2 x 40 mL R2: 2 x 10 mL
DZ113C-CAL	Enzymatic Potassium Calibrator Set (liquid stable)	Cal: 2 x 3 mL vial
DZ113C-CON	Enzymatic Potassium Control Set (lyophilized)	Con: 2 x 3 mL vial

DZ114B Enzymatic Sodium Assay 510(k) Cleared; EU:

Catalog No.	Description	Format
DZ114B-K01	Enzymatic Sodium Assay (liquid stable)	R1: 2 x 40 mL R2: 2 x 20 mL
DZ114B-CAL	Enzymatic Sodium Calibrator Set (liquid stable)	Cal: 2 x 3 mL vial
DZ114B-CON	Enzymatic Sodium Control Set (lyophilized)	Con: 2 x 3 mL vial

DZ116B Enzymatic Lithium Assay 510(k) Cleared; EU: ; Health Canada Registered

Catalog No.	Description	Format
DZ116B-KH1	Enzymatic Lithium Assay (liquid stable)	R1: 2 x 10 mL R2: 2 x 5 mL
DZ116B-CAL	Enzymatic Lithium Calibrator Set (liquid stable)	Cal: 3 x 3 mL vial
DZ116B-CON	Enzymatic Lithium Control Set (lyophilized)	Con: 2 x 3 mL vial

DZ122A Carbon Dioxide Enzymatic Assay 510(k) Cleared; EU:

Catalog No.	Description	Format
DZ122A-KY1	Carbon Dioxide Enzymatic Assay (liquid stable)	R1: 5 x 20 mL
DZ122A-CAL	Carbon Dioxide Calibrator (liquid stable)	Cal: 1 x 2 mL vial
DZ122A-CON	Carbon Dioxide Control Set (liquid stable)	Con: 2 x 2 mL vial

INFECTIOUS DISEASE MARKERS

DZ901A SARS CoV-2 Neutralizing Antibody CLIA Kit FDA EUA; EU:

Catalog No.	Description	Format
DZ901A	SARS-CoV-2 Neutralizing Antibody CLIA Kit	Magnetic beads: 1 x 2.75 mL Capture Reagent: 12.5 mL Detection Reagent: 12.5 mL Cal Low/High: 2 x 0.5 mL Con Low/High: 2 x 1.0 mL

130219015M DZ-Lite SARS-CoV-2 IgG CLIA Kit FDA EUA

Catalog No.	Description	Format
130219015M	DZ-Lite SARS-CoV-2 IgG CLIA Kit	Magnetic Microbeads: 1 x 2.5 mL ABEI Label: 1 x 23.5 mL Diluent: 1 x 23.5 mL Buffer: 1 x 23.5 mL Cal Low/High: 2 x 1.0 mL Con Set: 2 x 1.0 mL

130219016M DZ-Lite SARS-CoV-2 IgM CLIA Kit FDA EUA

Catalog No.	Description	Format
130219016M	DZ-Lite SARS-CoV-2 IgM CLIA Kit	Magnetic Microbeads: 1 x 2.5 mL ABEI Label: 1 x 23.5 mL Diluent: 1 x 23.5 mL Buffer: 1 x 23.5 mL Cal Low/High: 2 x 1.0 mL Con Set: 2 x 1.0 mL

INFLAMMATORY MARKERS

DZ135A hsCRP Assay 510(k) Cleared; EU:

Catalog No.	Description	Format
DZ135A-K	hsCRP Assay (liquid stable)	R1: 1 x 60 mL R2: 1 x 14 mL
DZ135A-CAL	hsCRP Calibrator Set (liquid stable)	Cal: 4 x 1 mL vial
DZ135A-CON	hsCRP Control Set (liquid stable)	Con: 3 x 3 mL vial

INFLAMMATORY MARKERS (Continued)

DZ178C Myeloperoxidase (MPO) Immunoassay EU: *

Catalog No.	Description	Format
DZ178C-K	Myeloperoxidase Immunoassay (liquid stable)	R1: 1 x 44 mL R2: 1 x 14 mL Cal: 5 x 1 mL vial
DZ178C-CON	Myeloperoxidase Control Set (liquid stable)	Con: 2 x 3 mL vial

IRRITABLE BOWEL DISEASE MARKERS

DZ202A Calprotectin Assay EU:

Catalog No.	Description	Format
DZ202A-KY1	Calprotectin Assay (liquid stable)	R1: 1 x 45 mL R2: 1 x 9.8 mL
DZ202A-CAL	Calprotectin Calibrator Set (liquid stable)	Cal: 5 x 1 mL vial
DZ202A-CON	Calprotectin Control Set (liquid stable)	Cal: 2 x 1 mL vial
DZ202A-CLDF	Diazyme Stool Sample Collection Vial	100 tubes/box (pre-filled)

LIVER MARKERS

DZ042A Total Bile Acids Assay 510(k) Cleared; EU: ; Health Canada Registered

Catalog No.	Description	Format
DZ042A-KY1	Total Bile Acids Assay (liquid stable)	R1: 2 x 60 mL R2: 2 x 20 mL
DZ042A-K01	Total Bile Acids Assay (liquid stable)	R1: 2 x 30 mL R2: 2 x 10 mL
DZ042A-CAL	Total Bile Acids Calibrator (liquid stable)	Cal: 1 x 2 mL vial
DZ042A-CON	Total Bile Acids Control Set (lyophilized)	Con: 3 x 1 mL vial



LIVER MARKERS (Continued)**DZ082B α -L-Fucosidase (AFU) Assay** EU:   *

*Available In Bulk Packaging Format Only - Cal/Con Compatible Material Is Also Available
(Please Contact The Diazyme Sales Department For More Information)*

Catalog No.	Description	Format
DZ082B-L	α -L-Fucosidase Assay, Bulk	R1: 1000 mL

DZ117A Adenosine Deaminase Assay EU:   *

Catalog No.	Description	Format
DZ117A-K	Adenosine Deaminase Assay (liquid stable)	R1: 1 x 50 mL R2: 1 x 25 mL
DZ117A-CAL	Adenosine Deaminase Assay Calibrators (lyophilized)	Cal: 1 x 1 mL vial
DZ117A-CON	Adenosine Deaminase Assay Controls (lyophilized)	Con: 2 x 1 mL vial

DZ123A 5'-Nucleotidase Assay 510(k) Exempt; EU:  ; Health Canada Registered

Catalog No.	Description	Format
DZ123A-K	5' - Nucleotidase Assay (liquid stable)	R1: 1 x 50 mL R2: 1 x 25 mL
DZ123A-CAL	5' - Nucleotidase Calibrator (lyophilized)	Cal: 1 x 1 mL vial
DZ123A-CON	5' - Nucleotidase Control Set (lyophilized)	Con: 2 x 1 mL vial

DZ062A N-Acetyl-β-D-Glucosaminidase (NAG) Assay EU:   *

Catalog No.	Description	Format
DZ062A-K	N-Acetyl-β-D-Glucosaminidase Assay (liquid stable)	R1: 1 x 75 mL R2: 1 x 15 mL R3: 1 x 30 mL
DZ062A-CAL	N-Acetyl-β-D-Glucosaminidase Calibrators (lyophilized)	Cal: 1 x 2 mL vial
DZ062A-CON	N-Acetyl-β-D-Glucosaminidase Controls (lyophilized)	Con: 2 x 2 mL vial

DZ072B Creatinine Liquid Reagent Assay 510(k) Cleared; EU:  

Catalog No.	Description	Format
DZ072B-KY1	Creatinine Liquid Reagent Assay (liquid stable)	R1: 2 x 60 mL R2: 2 x 20 mL
DZ072B-CAL	Creatinine Liquid Reagent Assay Calibrator (liquid stable)	Cal: 1 x 1 mL vial
DZ072B-CON	Creatinine Liquid Reagent Control (liquid stable)	Con: 1 x 1 mL vial

DZ132A Lipase Assay 510(k) Exempt; EU:  

Catalog No.	Description	Format
DZ132A-K	Lipase Assay (liquid stable)	R1: 2 x 50 mL R2: 2 x 11 mL
DZ132A-CAL	Lipase Calibrator (lyophilized)	Cal: 1 x 1 mL vial
DZ132A-CON	Lipase Controls (lyophilized)	Con: 2 x 5 mL vial

DZ133C Cystatin C Assay 510(k) Cleared; EU:  

Catalog No.	Description	Format
DZ133C-KY1	Cystatin C Assay (liquid stable)	R1: 1 x 60 mL R2: 1 x 12 mL
DZ133C-CAL	Cystatin C Calibrator Set (liquid stable)	Cal: 5 x 1 mL vial
DZ133C-CON	Cystatin C Control Set (liquid stable)	Con: 2 x 1 mL vial

SEPSIS MARKERS**DZ558A Procalcitonin (PCT) Assay** 510(k) Cleared; EU: **CE** **IVD**; Health Canada Registered

Catalog No.	Description	Format
DZ558A-KY1 USA Domestic Only	Procalcitonin Assay (liquid stable)	R1: 1 x 44 mL R2: 1 x 14 mL
DZ558A-K Export Only	Procalcitonin Assay (liquid stable)	R1: 1 x 44 mL R2: 1 x 14 mL
DZ558A-CAL	Procalcitonin Calibrator Set (lyophilized)	Cal: 6 x 1 mL vial
DZ558A-CON	Procalcitonin Control Set (lyophilized)	Con: 2 x 3 mL vial

VITAMIN MARKERS**DZ888A EZ Vitamin D Assay** 510(k) Cleared; EU: **CE** **IVD**

Catalog No.	Description	Format
DZ888A-K	EZ Vitamin D Assay (liquid stable)	R1: 1 x 40 mL R2: 1 x 10 mL
DZ888A-CAL	EZ Vitamin D Calibrator Set (liquid stable)	Cal: 5 x 1 mL vial
DZ888A-CON	EZ Vitamin D Control Set (liquid stable)	Con: 2 x 3 mL vial

* SKU For Export Only: Not for Distribution in the USA.

USA: Research Use Only.

Not For Use in Diagnostic Procedures.

CANCER MARKERS

DZ863B Carcinoembryonic Antigen Assay USA: For Research Use Only*

*Available In Bulk Packaging Format Only - Cal/Con Compatible Material Is Also Available
(Please Contact The Diazyme Sales Department For More Information)*

Catalog No.	Description	Format
DZ863B-R1L	Carcinoembryonic Antigen Assay, Bulk Reagent 1	R1: 800 mL
DZ863B-R2L	Carcinoembryonic Antigen Assay, Bulk Reagent 2	R2: 200 mL

DZ869B Alpha-Fetoprotein Assay USA: For Research Use Only*

*Available In Bulk Packaging Format Only - Cal/Con Compatible Material Is Also Available
(Please Contact The Diazyme Sales Department For More Information)*

Catalog No.	Description	Format
DZ869B-R1L	Alpha-Fetoprotein Assay, Bulk Reagent 1	R1: 800 mL
DZ869B-R2L	Alpha-Fetoprotein Assay, Bulk Reagent 2	R2: 200 mL

CARDIOVASCULAR MARKERS

DZ560A Small Dense Low-Density Lipoprotein-Cholesterol (sdLDL) Assay USA: For Research Use Only*

Catalog No.	Description	Format
DZ560A-K	Small Dense Low-Density Lipoprotein-Cholesterol (sdLDL) Assay (liquid stable)	R1: 1 x 46 mL R2: 1 x 18.8 mL
DZ560A-CAL	Diazyme sdLDL Calibrator Set (lyophilized)	Cal: 1 x 2 mL vial
DZ560A-CON	Diazyme HDL3 / sdLDL Control Set (lyophilized)	Con: 1 x 2 mL vial

DZ561A High-Density Lipoprotein III (HDL3) Assay USA: For Research Use Only*

Catalog No.	Description	Format
DZ561A-K	High-Density Lipoprotein (HDL3) Assay (liquid stable)	R1: 1 x 40 mL R2: 1 x 17 mL
DZ561A-CAL	Diazyme HDL3 Calibrator Set (lyophilized)	Cal: 2 x 2 mL vial
DZ560A-CON	Diazyme HDL3 / sdLDL Control Set (lyophilized)	Con: 1 x 2 mL vial

CARDIOVASCULAR MARKERS *(Continued)***DZ567A** **Diazyme ST2 Assay** USA: For Research Use Only**Coming Soon*

Catalog No.	Description	Format
DZ567A-KY1	Diazyme ST2 Assay (liquid stable)	R1: 1 x 35 mL R2: 1 x 9 mL
DZ567A-CAL	Diazyme ST2 Calibrator Set (lyophilized)	Cal: 6 x 1 mL vial
DZ567A-CON	Diazyme ST2 Control Set (lyophilized)	Con: 2 x 1 mL vial

DZ785B **Heart-Type Fatty Acid-Binding Protein** USA: For Research Use Only*
(H-FABP) Assay*Available In Bulk Packaging Format Only - Cal/Con Compatible Material Is Also Available
(Please Contact The Diazyme Sales Department For More Information)*

Catalog No.	Description	Format
DZ785B-R1L	Heart-Type Fatty Acid-Binding Protein (H-FABP) Assay, Bulk Reagent 1	R1: 800 mL
DZ785B-R2L	Heart-Type Fatty Acid-Binding Protein (H-FABP) Assay, Bulk Reagent 2	R2: 200 mL

DIABETIC MARKERS**DZ188A** **Adiponectin Assay** USA: For Research Use Only*

Catalog No.	Description	Format
DZ188A-KY1	Adiponectin Assay (liquid stable)	R1: 1 x 43 mL R2: 1 x 11.5 mL
DZ188A-CAL	Adiponectin Calibrator Set (lyophilized)	Cal: 5 x 1 mL vial
DZ188A-CON	Adiponectin Control Set (lyophilized)	Con: 2 x 1 mL vial

INFLAMMATORY MARKERS

DZ178D Myeloperoxidase (MPO) Immunoassay USA: For Research Use Only*

Catalog No.	Description	Format
DZ178D-K	Myeloperoxidase Immunoassay (liquid stable)	R1: 1 x 44 mL R2: 1 x 14 mL Cal: 5 x 1 mL vial
DZ178D-CON	Myeloperoxidase Control Set (liquid stable)	Con: 2 x 3 mL vial

IRRITABLE BOWEL DISEASE MARKERS

DZ137A Lactoferrin Assay USA: For Research Use Only*

Catalog No.	Description	Format
DZ137A-KY1	Lactoferrin Assay (liquid stable)	R1: 1 x 30 mL
DZ137A-CAL	Lactoferrin Assay Calibrator Set (liquid stable)	R2: 1 x 10 mL
DZ137A-CON	Lactoferrin Assay Control Set (liquid stable)	Cal: 5 x 1 mL vial
DZ202A-CLDF	Diazyme Stool Sample Collection Vial	Con: 2 x 1 mL vial 100 tubes/box (pre-filled)

LIVER MARKERS

DZ082C α -L-Fucosidase (AFU) Assay USA: For Research Use Only*

*Available In Bulk Packaging Format Only - Cal/Con Compatible Material Is Also Available
(Please Contact The Diazyme Sales Department For More Information)*

Catalog No.	Description	Format
DZ082C-L	α -L-Fucosidase Assay, Bulk	R1: 1000 mL

DZ117C Adenosine Deaminase Assay USA: For Research Use Only*

Catalog No.	Description	Format
DZ117C-K	Adenosine Deaminase Assay (liquid stable)	R1: 1 x 50 mL R2: 1 x 25 mL
DZ117C-CAL	Adenosine Deaminase Assay Calibrators (lyophilized)	Cal: 1 x 1 mL vial
DZ117C-CON	Adenosine Deaminase Assay Controls (lyophilized)	Con: 2 x 1 mL vial

LUNG DISEASE MARKERS

DZ902A DZ-Lite MMP-1 CLIA Kit USA: For Research Use Only*

Catalog No.	Description	Format
DZ902A-CLIA	DZ-Lite MMP-1 CLIA Kit	Nano magnetic microbeads: 1 x 2.5 mL ABEI Label 12.5 mL Cal Low/High: 2 x 1.0 mL Con Low/High: 2 x 1.0 mL

DZ903A DZ-Lite MMP-7 CLIA Kit USA: For Research Use Only*

Catalog No.	Description	Format
DZ903A-CLIA	DZ-Lite MMP-7 CLIA Kit	Nano magnetic microbeads: 1 x 2.5 mL ABEI Label 12.0 mL Cal Low/High: 2 x 1.0 mL Con Low/High: 2 x 1.0 mL

RENAL AND PANCREATIC MARKERS

DZ062B N-Acetyl-β-D-Glucosaminidase (NAG) Assay USA: For Research Use Only*

Catalog No.	Description	Format
DZ062B-K	N-Acetyl-β-D-Glucosaminidase Assay (liquid stable)	R1: 1 x 75 mL R2: 1 x 15 mL R3: 1 x 30 mL
DZ062B-CAL	N-Acetyl-β-D-Glucosaminidase Calibrators (lyophilized)	Cal: 1 x 2 mL vial
DZ062B-CON	N-Acetyl-β-D-Glucosaminidase Controls (lyophilized)	Con: 2 x 2 mL vial

SEPSIS MARKERS

DZ626A Serum Amyloid A (SAA) Assay USA: For Research Use Only*

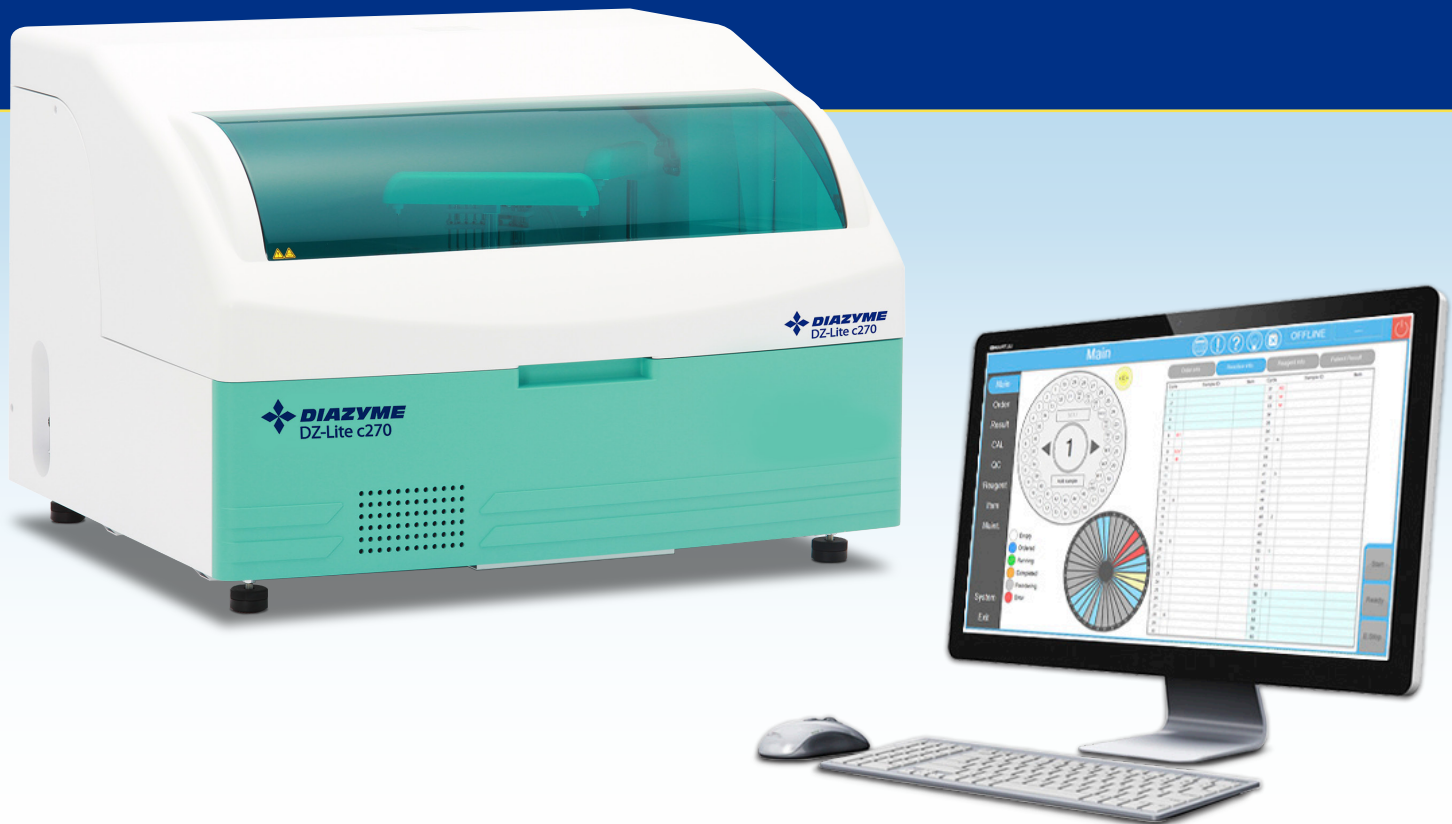
Catalog No.	Description	Format
DZ626A-KY1	Serum Amyloid A (SAA) Assay (liquid stable)	R1: 1 x 60 mL R2: 1 x 15 mL
DZ626A-CAL	Serum Amyloid A (SAA) Calibrator Set (lyophilized)	Cal: 5 x 1 mL vial
DZ626A-CON	Serum Amyloid A (SAA) Control Set (lyophilized)	Con: 2 x 1 mL vial

* USA: For Research Use Only. Not For Use In Diagnostic Procedures.



DZ-Lite™ c270

A Fully-Automated, Reliable, Bench-Top Solution



INNOVATIVE ASSAY MENU

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SUPPORTS 1, 2, 3 & 4-REAGENT ASSAYS

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DZ-LITE c270 ASSAY MENU

IVD

- Apolipoprotein A-1
- Apolipoprotein B
- Beta-Hydroxybutyrate♦
- Calprotectin
- Carbon Dioxide Enzymatic
- Creatinine Liquid Reagent
- Cystatin C
- D-Dimer
- Direct Enzymatic HbA1c
- Direct HbA1c
(Enzymatic, On-Board Lysis)
- Enzymatic Lithium
- Enzymatic Potassium
- Enzymatic Sodium
- EZ Vitamin D
- Glycated Serum Protein

IVD (continued)

- HDL-Cholesterol
- Homocysteine
- hsCRP
- Human Kappa FLC
- Human Lambda FLC
- LDL-Cholesterol
- Lipase♦
- Pancreatic Elastase
(Coming Soon)
- Lipoprotein (a)
- PLAC® Test
for Lp-PLA2 Activity
- Procalcitonin
- Total Bile Acids
- 1,5-Anhydroglucitol (1,5-AG)
- 5'-Nucleotidase♦

USA: For Research Use Only*

- Adenosine Deaminase
- Adiponectin
- Cardiac Troponin I
- HDL3
- Lactoferrin
- Myeloperoxidase (MPO)
- N-Acetyl-β-D-Glucosaminidase (NAG)
- Serum Amyloid A (SAA)
(Coming Soon)
- sdLDL
- ♦ Not CLIA Categorized
- * USA: For Research Use Only.
Not For Use In Diagnostic Procedures



Instrument:  510(k) Cleared

DZ-Lite c270 Third Party CLIA Assay Menu

GENERAL CHEMISTRIES - REAGENTS				
Catalog No.	Assay	Format	Regulatory Status	CR #
BL224	ALB (Albumin)	3 x 160 tests	510(k) Cleared	CR200329
BL206	ALP (Alkaline Phosphate)	3 x 100 tests	510(k) Cleared	CR200338
BL240	ALT (Alanine Aminotransferase)	3 x 100 tests	510(k) Exempt	CR200334
BL227	AMY (Amylase)	3 x 170 tests	510(k) Cleared	CR200502
BL241	AST (Aspartate Aminotransferase)	3 x 100 tests	510(k) Exempt	CR200336
BL252	BUN (Blood Urea Nitrogen)	3 x 170 tests	510(k) Cleared	CR200335
BL251	CA (Calcium)	3 x 160 tests	510(k) Cleared	CR200339
IR050-R	Chloride (Photometric)	1 x 80 mL	510(k) Cleared	CR200483
BL211	CHOL (Cholesterol)	3 x 100 tests	510(k) Cleared	CR200495
BL207	CK (Creatine Kinase)	3 x 100 tests	510(k) Cleared	CR200337
BL228	TBIL (Total Bilirubin)	3 x 100 tests	510(k) Cleared	CR200513
BL229	DBIL (Direct Bilirubin)	3 x 100 tests	510(k) Cleared	CR200503
BL209	GGT (Gamma-Glutamyl Transferase)	3 x 100 tests	510(k) Exempt	CR200498
BL208	GLU (Glucose)	3 x 110 tests	510(k) Cleared	CR190001
DT618	IRON (Iron) w/cal	R1: 3 x 68 mL, R2: 3 x 12 mL Estimated 1000 tests/kit	510(k) Exempt	CR200514
BL205	LDH (Lactate Dehydrogenase)	3 x 100 tests	510(k) Exempt	CR200496
AU-621	LIP (Lipase) w/cal	R1: 3 x 17 mL, R2: 3 x 5 mL Estimated 250 tests/kit	510(k) Exempt	CR200510
BL218	PHOS (Phosphorus)	3 x 170 tests	510(k) Exempt	CR200509
BL217	TP (Total Protein)	3 x 160 tests	510(k) Exempt	CR200497
BL213	TRIG (Triglycerides)	3 x 100 tests	510(k) Cleared	CR210376
BL212	URIC (Uric Acid)	3 x 160 tests	510(k) Exempt	CR200331
GENERAL CHEMISTRIES - CALIBRATORS				
CC465915	BILI (Bilirubin, Total and Direct) Calibrator	10 x 1 mL	510(k) Cleared	
IR050-CAL-K	Chloride (Photometric) Calibrator	Low: 1 x 50 mL High: 1 x 50 mL	510(k) Cleared	
28200	Serum Calibrator	6 x 5 mL	510(k) Cleared	
GENERAL CHEMISTRIES - SUPPLEMENTAL CALIBRATORS				
CC618-STD	IRON (Iron) Supplemental Calibrator Std	1 x 5 mL	510(k) Cleared	
27401S	LIP (Lipase) Supplemental Calibrator Std	1 x 1 mL	510(k) Exempt	
GENERAL CHEMISTRIES - CONTROLS				
CC23-640065	MAS™ chemTRAK® Lvl 1 Control (Gen Chem, Electrolytes, Enzymes, Lipids & T4)	6 x 5 mL	510(k) Cleared	
CC23-640066	MAS™ chemTRAK® Lvl 2 Control (Gen Chem, Electrolytes, Enzymes, Lipids & T4)	6 x 5 mL	510(k) Cleared	
CC23-640067	MAS™ chemTRAK® Lvl 3 Control (Gen Chem, Electrolytes, Enzymes, Lipids & T4)	6 x 5 mL	510(k) Cleared	

Products not available for export

DZ-Lite c270 Third Party CLIA Assay Menu

DRUGS OF ABUSE - REAGENTS				
Catalog No.	Assay	Format	Regulatory Status	CR #
DZC347UR-0100	6-Acetylmorphine (6AM)	100 mL	510(k) Cleared	CR230369
DZC309UR-0100	Amphetamine (AMPH)	100 mL	510(k) Cleared	CR230369
DZC310UR-0100	Barbiturate (BARB)	100 mL	510(k) Cleared	CR230369
DZC313UR-0100	Benzodiazepines (BENZ)	100 mL	510(k) Cleared	CR230369
DZC336UR-0100	Buprenorphine (BUP)	100 mL	510(k) Cleared	CR230369
DZC305UR-0100	Cannabinoids (carboxy-THC)	100 mL	510(k) Cleared	CR230369
DZC306UR-0100	Cocaine/Benzoylecgonine (COCM)	100 mL	510(k) Cleared	CR230369
DZC349UR-0100	Methadone Metabolite (EDDP)	100 mL	510(k) Cleared	CR230369
DZC311UR-0100	Methamphetamine (METH)	100 mL	510(k) Cleared	CR230369
DZC307UR-0100	Opiates	100 mL	510(k) Cleared	CR230369
DZC302UR-0100	Oxycodone (OXYC)	100 mL	510(k) Cleared	CR230369
DZC308UR-0100	Phencyclidine (PCP)	100 mL	510(k) Cleared	CR230369
DZC618UR-0100	Sefria Fentanyl (FENT)	100 mL	510(k) Cleared	CR230369
DZC304UR-0100	Tramadol (TRAM)	100 mL	510(k) Cleared	CR230369
DRUGS OF ABUSE - CALIBRATORS				
DZC10006	6AM, 10 ng/mL Calibrator	1 x 5 mL	510(k) Cleared	
DZCC309UR-5-1-500	Amphetamine (AMPH) Cal, 500 ng/mL	1 x 5 mL	510(k) Cleared	
DZCC309UR-5-1-1000	Amphetamine (AMPH) Cal, 1000 ng/mL	1 x 5 mL	510(k) Cleared	
DZCC314UR-5-1-200	Benzodiazepines Urine, 200 ng/mL	1 x 5 mL	510(k) Cleared	
DZCC336UR-10-1	Buprenorphine (BUP) Cal, 5 ng/mL	1 x 10 mL	510(k) Cleared	
DZC10012-5	Cannabinoids (carboxy-THC) Cal, 50 ng/mL	1 x 5mL	510(k) Cleared	
DZC10019-5	Sefria FENT (Fentanyl) Calibrator 1.0 ng/mL	1 x 5 mL	510(k) Cleared	
DZCNEG-600-5	Sefria FENT (Fentanyl) Negative Standard	1 x 5 mL	510(k) Cleared	
DZC10016-5	Methadone Metabolite (EDDP) Cal, 300 ng/mL	1 x 5 mL	510(k) Cleared	
DZC10000-15	Multi-drug Calibrator Level 1	1 x 5 mL	510(k) Cleared	
DZC10001-15	Multi-drug Calibrator Level 2	1 x 5 mL	510(k) Cleared	
DZCNEG-10-1	Negative Urine Calibrator	1 x 10 mL	510(k) Cleared	
DZC10008-5	Opiates Urine, 2000 ng/mL	1 x 5 mL	510(k) Cleared	
DZCC302UR-10-1-100	Oxycodone (OXYC) Cal, 100 ng/mL	1 x 10 mL	510(k) Cleared	
DZCC302UR-10-1-300	Oxycodone, 300 ng/mL	1 x 10 mL	510(k) Cleared	
DZCC304UR-10-1	TRAM (Tramadol) 200 ng/mL Cutoff Calibrator	1 x 10 mL	510(k) Cleared	

Products not available for export

DZ-Lite c270 Third Party CLIA Assay Menu

DRUGS OF ABUSE - CONTROLS				
Catalog No.	Assay	Format	Regulatory Status	CR #
DZC3004-5	6AM 7.5 ng/mL & 12.5 ng/mL Control	2 x 5 mL	510(k) Cleared	
DZCC309UR-5-2-500	Amphetamine Control - 375 ng/mL & 625 ng/mL	2 x 5 mL	510(k) Cleared	
DZCC309UR-5-2-1000	Amphetamine Control - 750 ng/mL & 1250 ng/mL	2 x 5 mL	510(k) Cleared	
DZCC336UR-10-2	Buprenorphine (BUP) Control, 3.75 ng/mL & 6.25 ng/mL	2 x 10 mL	510(k) Cleared	
DZC3005-15	THC Control Set - 37.5 and 62.5 ng/mL	2 x 15 mL	510(k) Cleared	
DZC3009-5	Sefria FENT (Fentanyl) 0.5 and 1.5 ng/mL control set	2 x 5 mL	510(k) Cleared	
DZC3007-5	Methadone Metabolite (EDDP) Control Set, 225 and 375 ng/mL	2 x 5 mL	510(k) Cleared	
DZC3000-15	Multi Drug Control Set 1	2 x 15 mL	510(k) Cleared	
DZC3001-15	Multi Drug Control Set 2	2 x 15 mL	510(k) Cleared	
DZC3001-15	Opiates Control Set, 1500 and 2500 ng/mL	2 x 15 mL	510(k) Cleared	
DZCC302UR-10-2-100	Oxycodone (OXYC) Control, 75 ng/mL & 125 ng/mL	2 x 10 mL	510(k) Cleared	
DZCC302UR-10-2-300	Oxycodone, 225 and 375 ng/mL	2 x 10 mL	510(k) Cleared	
DZCC304UR-10-2	TRAM (Tramadol), 150 and 250 ng/mL control	2 x 10 mL (2 lev)	510(k) Cleared	



DZ-Lite 3000 Plus

Chemiluminescence Immunoassay System (CLIA)



INTEGRATED DESIGN

SIMPLE AND SMART OPERATION

COMPACT SIZE AND WEIGHT

CE 510(k) Cleared

DZ-Lite™ 3000 Plus

Chemiluminescence Immunoassay System (CLIA)

TECHNICAL SPECIFICATIONS	
Reagent Features	<ul style="list-style-type: none">• Flash chemiluminescence label – ABEI, with high sensitivity and long stability• Magnetic microbeads separation, fast and efficient
Main Features	<ul style="list-style-type: none">• Throughput: up to 180 tests/hour• 24 hours ready-to-use• Time to first result: 17 minutes
Modes of Operation	<ul style="list-style-type: none">• Random, Batch and STAT
Sample Loading	<ul style="list-style-type: none">• Up to 144 sample tubes• Continuous loading, STAT available• Barcode reader recognition or analyzer automatic numbered• LIS connection, automatic read sample information• Refrigerated sample area with independent power supply
Reagent Loading	<ul style="list-style-type: none">• 25 reagents on board• Continuous loading• RFID reading all info of reagent• Refrigerated reagent area with independent power supply
Reagent Integral	<ul style="list-style-type: none">• Ready-to-use, no pretreatment required• Including calibrators• RFID tag storing all info of reagent• RFID tag with built-in master curve• 2-point calibration to adjust master curve• Calibration stability: Max 4 weeks
Other Features	<ul style="list-style-type: none">• Clot detection• Liquid level detection• Automatic and optional ratio for high sample dilution• Constant $36.8 \pm 0.5^{\circ}\text{C}$ incubation
Operation System	<ul style="list-style-type: none">• Windows 10• Dell compatible (Dual-core CPU)• Color touch screen
Interconnection	<ul style="list-style-type: none">• Bidirectional LIS connection by TCP/IP and COM
Dimensions Weight	<ul style="list-style-type: none">• Input: AC 110/230 Vac. 50/60 Hz• Dimension and weight: 144*76*152cm 228kg

Note: Printer not included. Printer must be compatible with Windows 10 operating system.

NOTES

A series of 20 horizontal light blue bars, stacked vertically, intended for taking notes. Each bar is uniform in color and width, spanning most of the page's width.

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