



# Biochemistry Analyzer

KIHT Technical Compendium

# BIOCHEMISTRY ANALYZER

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Version 1.0

**Acknowledgment:**

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## LIST OF ABBREVIATIONS

<b>Acronym</b>	<b>Definition</b>
ACTH	Adrenocorticotrophic hormone
ADC	Analog to digital converter
AIMDD	Active Implantable Medical Devices Directive
ALP	Alkaline phosphatase
ALT	Alanine transaminase
AST	Aspartate transaminase
ASTM	American Society for Testing and Materials
BNP	B-type natriuretic peptide
BUN	Blood urea nitrogen
CAGR	Compounded Annual Growth Rate
CDRH	Center for Devices and Radiological Health
CE	European Conformity
CK	Creatinine Kinase
CSF	Cerebro Spinal Fluid
DNA	De-oxyribo Nucleic Acid
EMF	Electro-motive Force
EU	European Union
EXIM	Export Import
FA	Fully Automated
FDA	Food and Drug Administration
FOBT	Fecal occult blood test
GGT	Gamma-glutamyl, transpeptidase
GMP	Good Manufacturing Practice
HITU	High-intensity therapeutic ultrasound
HS	Harmonizing Standards
IDF	International Diabetes Federation
IEC	International Electrotechnical Committee

<b>Acronym</b>	<b>Definition</b>
INR	Indian National Rupee
IP	Intellectual Property
IR	Infrared
IRMA	Immunoradiometric Assay
ISE	Ion Selective Electrode
ISO	International Organization for Standardization
IU	International Unit
IVDMDD	In-vitro Diagnostic Medical Device Directive
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LIMS	Laboratory Information Management System
LIS	Laboratory Information System
MDD	Medical Device Directive
ME	Medical Equipment
NABL	National Accreditation Board for Testing and Calibration Laboratories
NCD	Non-communicable Diseases
NIRS	Near-infra red spectroscopy
NSE	Neuron-specific enolase
PMA	Pre-market Authorization
PMS	Post-market Surveillance
PNP	Positive-negative-positive
QC	Quality control
RFID	Radio frequency identification
RIA	Radioimmunoassay
RNA	Ribonucleic Acid
RTD	Resistance Temperature Detectors
SA	Semi-Automated
TCP	Transmission Control Protocol

<b>Acronym</b>	<b>Definition</b>
TIBC	Total iron binding capacity
TLA	Total Lab Automation
UPS	Uninterruptible Power Supply
USB	Universal Serial Bus
USD	United States Dollar
UV	Ultraviolet
VA	Volts Ampere
VAC	Volts Alternating Current
VIS	Visible Spectroscopy

## **EXECUTIVE SUMMARY**

Currently, various technologies are used to analyze the proteins, genes, enzymes, and other analytes that are indications to one degree or another of a health problem and test for infections (diagnostic testing). The vast majority of diagnostic testing is conducted using diagnostic technologies in laboratory settings. The most widely used techniques are optics-based measurements and examples include colorimetric, absorption, spectrometric and fluoroscopic detection methods. These processes can measure molecules, chemicals such as antigens and proteins in body fluids such as blood, urine, saliva, and sometimes, cerebrospinal fluid, or secretions and cells from the nose, throat, vagina, or an open wound. These techniques are widely used in hospitals, clinics, epidemic prevention stations, and family planning service providers because of their fast measurement ability, high sensitivity, and accuracy when detecting even small doses of chemicals.

By one estimate, more than seven billion diagnostic tests are performed every year globally. Results from these tests allow health care providers and their patients to better understand a person's health status, and to make informed decisions. Through reporting and monitoring programs, many of these results will also impact public health at the local and national levels. One of the majorly used diagnostic devices is biochemistry analyzer.

A biochemistry analyzer is a clinical laboratory instrument designed to determine the concentration of certain metabolites, electrolytes, proteins, and/or drugs in biological samples like whole blood, serum, plasma, urine, cerebrospinal fluid, and/or other body fluids, quickly with minimal human assistance for diagnosis of diseases.

The biochemical analyzer is a complex system composed of an optical engine consisting of light sources, detectors and other optical elements, sample movement/fluidics, automation control and processing, power management, and environmental monitoring and control (temperature, pressure, humidity). For greater efficiency, biochemical analyzers have become highly automated. This technology automates sample loading, tube cleaning, mechanical control, and data processing. The operator just needs to insert the sample for analysis, choose the program, and start the instrument.

According to "Medical Buyer report", the Indian market for biochemistry instruments and reagents in 2017 is estimated at Rs. 1540 crore, with reagents dominating with an 81 percent market share. The global biochemistry analyzers market was valued at USD 3.1 billion in 2017 and is projected to reach USD 5 billion by 2026, exhibiting a CAGR of 5.4 percent, projects

## **ABOUT:**

Andhra Pradesh MedTech Zone (AMTZ) is an enterprise under the Government of Andhra Pradesh, a 270 Acre zone dedicated for medical device manufacturing with 200-250 manufacturing units. AMTZ provides the one-stop solution for all the manufacturers by providing, common scientific testing facilities (EMI/EMC, Electrical Safety, Radiation, Biomaterials Testing, 3D printing facilities), commercial facilities such as expo halls and warehouse.

Kalam Institute of Health Technology (KIHT) in the premises of AMTZ facilitates focused research on critical components pertaining to medical devices, technology transfer of innovative technologies through e-auction, market innovation, and access. These end to end solutions help to reduce the cost of manufacturing up to 40% and make health care products more affordable and accessible.

## **For Orders:**

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