भारतीय मानक

Indian Standard

IS 17717 (Part 2) : 2023

इन-विट्रो डायग्नोस्टिक (आईवीडी) उपकरणों — स्वचालित क्लिनिकल रसायन विज्ञान विश्लेषक

भाग 2 शुष्क रसायन विश्लेषक

In-Vitro Diagnostic (IVD) Device — Automated Clinical Chemistry Analyzer

Part 2 Dry Chemistry Analyzer

ICS 11.100.10

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
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December 2023 **Price Group 7**

FOREWORD

This Indian Standard (Part 2) was adopted by Bureau of Indian Standards, after the draft finalized by the In-vitro diagnostic medical devices and biological evaluation of medical devices Sectional Committee had been approved by Medical Equipment and Hospital Planning Division Council.

This standard is published in two parts. Other part in this series of Performance Testing of *In-vitro* Diagnostic (IVD) Instruments — Automated Clinical chemistry Analyzer is:

Part 1 Wet chemistry analyzer

This standard provides basic requirements and standard test procedures for performance testing of *In-Vitro* diagnostic (IVD) instruments — Automated clinical chemistry analyzers that are used in all types of laboratories, from small point-of-care clinics to high-throughput clinical labs, to test for analytes such as proteins, enzymes, and electrolytes. Applications include monitoring diseases such as diabetes, testing for metabolic functions or cardiac markers, and drugs-of-abuse testing amongst others. Benchtop analyzers are the most common type, but compact bedside models, usually with fewer test options, and high-throughput floor-based units are also available.

The Committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards/ Other Publications and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
CLSI EP09-A3	Measurement procedure comparison and bias estimation using patient samples, 3rd addition
CLSI EP06-A	Evaluation of the linearity of quantitative measurement procedures: A statistical approach, 1st edition
CLSI EP15-A3	User verification of precision and estimation of bias

The list of abbreviations are given in Annex A.

The composition of the Committee responsible for the formulation of this standard is given in Annex B.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

PERFORMANCE TESTING OF IN-VITRO DIAGNOSTIC (IVD) INSTRUMENTS — AUTOMATED CLINICAL CHEMISTRY ANALYZER

PART 2 DRY CHEMISTRY ANALYZER

1 SCOPE

This part of Indian standard provides basic requirements and standard test procedures for performance testing of In-Vitro diagnostic (IVD) instruments — Automated clinical chemistry Analyzers also known as Biochemistry Analyzers including random access, high throughput fully automated clinical chemistry analysers for dry chemistry analyzer only.

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of these standards:

IS No.	*Title*
IS/IEC 61010-1 : 2010	Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements
IS/ISO 13485 : 2016	Medical Devices — Quality management systems — Requirements for regulatory purposes (*first revision*)
IS/ISO 14971 : 2007	Medical devices — Application of risk management to medical devices
IS 17724 (Part 4) : 2023	Safety requirements for electrical equipment for measurement, control, and laboratory use: Part 4 Particular requirements for in-vitro diagnostic (IVD) medical equipment
IS 17784 (Part 2) : 2023	Electrical equipment for measurement, control and laboratory use — EMC requirements: Part 2 Particular requirements for in-vitro diagnostic (IVD) medical equipment

3 TERMS AND DEFINITIONS

3.1 Linearity

The ability (within a given range) to provide results that are directly proportional to the concentration of the analyte in the test sample.

3.2 Precision

Closeness of measured quantity values obtained by replicate measurements on the same instrument under specified conditions.

3.3 Outlier

The observation in a study, so far separated in value from the remainder as to suggest that it may be from a different population, or the result of an error in measurement.

3.4 Accuracy

Closeness between a measured quantity value and a true quantity value of a measurand.

3.5 Throughput

Number of tests conducted by machine per hour

4 PRINCIPLE

Dry chemistry analyzers use measurement technologies including reflectometry and ion-selective potentiometry principle to analyse samples such as blood serum, plasma, urine and cerebrospinal fluid. Critical blocks of biochemistry analyzers below are provided as an illustration in Fig. 1. It may vary from model to model depending upon the claims and specifications of the manufacturer.

The biochemistry analyzer has the following critical blocks as illustrated in the Fig. 1:

a) Sample metering sub-system;
b) Reagent (dry chemistry reagents) supply system;
c) Incubator;
d) Reflectometer for reading reflectance density (dr) of end-point chemistry, two-point kinetic chemistry, multi-point kinetic chemistry and immune-rate chemistry; and
e) Electrometer for measuring potential difference between test and reference electrode. Operating system with computer (built-in or standalone) and monitor.

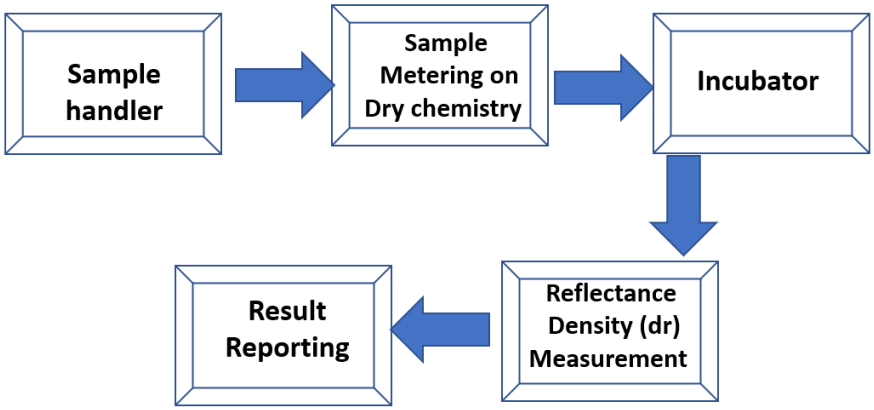


FIG. 1 BLOCK DIAGRAM OF DRY CHEMISTRY SYSTEM

(*Clause* 4.1)

5 REQUIREMENTS

5.1 Safety Requirements

The instrument shall comply with the specifications of IS/IEC 61010-1.

5.2 EMC Requirements

The instrument shall comply with the specifications of IS 17784 (Part 2)/IEC 61326-2-6.

6 PERFORMANCE EVALUATION, CHARACTERISTICS AND SPECIFICATIONS

Procedures below are provided as illustrations. They may vary from model to model depending upon the claims and specifications of the manufacturer.

In dry chemistry system, since there is no any liquid reagent, the performance evaluation of the dry chemistry system shall be verified for its performance in terms of precision and accuracy of the selected marker chemistries based on the assay principle like endpoint chemistry, two-point rate chemistry, multi-point kinetic chemistry, Immuno-rate chemistry and potentiometric chemistry. This will help in verifying the sample metering accuracy of the system, incubator temperature verification and the measurement system like reflectometer and electrometer of the dry chemistry system. Further the analytical measurement range of the system can be verified with the selected marker chemistry.

6.1 Precision and Accuracy Verification of the System using Selected Marker Chemistry

Verification of precision should be conducted as per the specifications provided in **CLSI EP15-A3**.

Accuracy should be conducted as per as per the specifications provided in **CLSI EP09-A3**:

a) First select the marker chemistry based on the assay principle, and load the reagent in the dry chemistry system as per the requirement;

b) Calibrate the marker chemistry, if not calibrated already. If calibrated, you may use the same calibration;

c) Before using the calibration for doing precision and accuracy verification, please ensure the calibration verification is done and accepted as per the manufacturer's recommendation;

d) Select two level control, one having the expected value within the reference range and second one having the expected value in the pathological range and below the upper measurement range of the assay;

e) Load the sample in the Dry chemistry system and program the test with 20 replicates, if the system is fully automated system;

f) Perform the test as per the manufacturer's instructions;

g) Repeat the same test for about 20 times;

h) Record all the 20 values for both level of controls;

j) Calculate the mean and standard deviation for all the 20 values, using the formula or any statistical tool;

k) From the mean and the standard deviation for both level of controls, calculate the co-efficient of variation (CV percent);

m) The CV percent shall be below 5 percent or as agreed between manufacturer and purchaser;

n) For the accuracy verification, compare the mean value obtained with the expected value;

p) Calculate the bias percent of obtained mean value from the expected value by using the following formula:

$$\text{Bias (\%)} = \frac{\text{Obtained value (Mean)} - \text{Expected Value}}{\text{Expected value}} \times 100$$

q) The Bias percent shall be below 5 percent or as agreed between manufacturer and purchaser.

6.2 Linearity Verification of the System Using Marker Chemistry

Linearity verification should be conducted as per **CLSI EP06-A**, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach Approved Guideline.

Linearity or Analytical measurement range verification study needs to be performed to determine the linear reportable range for an analyte on the instrument in line with the claims and specifications of the manufacturer.

a) First select the marker chemistry based on the assay principle, and load the reagent in the Dry chemistry system as per the requirement;

b) Calibrate the marker chemistry, if not calibrated already. If calibrated, you may use the same calibration;

c) Before using the calibration for doing linearity verification, please ensure the calibration verification is done and accepted as per the manufacturer's recommendation;

d) Select two samples or controls or calibrators — one having the value close to the lower analyte measurement range and second one having the value close to the upper analyte measurement range. For example, if the analyte measurement range of the marker chemistry is from 50 units to 500 units, the first level may have the value between 50 units to 55 units and the second level may have the value between 450 units to 500 units;

e) With these two levels of samples or controls or calibrators, prepare 5 different concentrations as follows:

1) Concentration 1 — Level 1 sample/ control/calibrator;

2) Concentration 2 — 3 part of Level 1 + 1 part of Level 2;

3) Concentration 3 — 1 part of Level 1 + 1 part of Level 2;

4) Concentration 4 — 1 part of Level 1 + 3 part of Level 2; and

5) Concentration 5 — Level 2 sample/ control/calibrator.

f) Perform the test using all 5 concentrations in duplicate in the Dry Chemistry system;

g) Record the obtained results for all the 5 concentrations;

h) For the test performed in duplicate, calculate the mean value for all the 5 concentrations;

j) Compare the obtained value with the expected value for all the 5 concentrations;

k) The expected value for the above mentioned 5 concentrations can be calculated as follows:

1) Concentration 1 — Value of level 1 sample/control/calibrator (X);

2) Concentration 5 — Value of level 2 sample/control/calibrator (Y);

3) Concentration 2 — (3X+1Y)/4;

4) Concentration 3 — (X+Y)/2; and

5) Concentration 4 — (1X+3Y)/4.

m) Plot the obtained value of each concentration on the Y-axis and the expected value on X-axis;

n) Perform linear regression analysis;

p) Estimate the slope, intercept and coefficient of co-relation (r); and

q) Linearity shall be agreed when the co-relation coefficient r^2 value is > 0.95 with the Slope: 1 ± 0.05 and Intercept tends to 0 or agreed between manufacturer and purchaser.

6.3 Calibration and Result Calculations

6.3.1 Calibration Curves

Calibration curves are used to understand the instrumental response to an analyte and predict the concentration in an unknown sample. Generally, a set of standard samples are made at various concentrations with a range than includes the unknown of interest and the instrumental response at each concentration is recorded. For more accuracy and to understand the error, the response at each concentration can be repeated so an error bar is obtained. The data are then fit with a function so that

unknown concentrations can be predicted using various curves.

6.3.2 The analyzer should have the provision to calculate results using one or more of the below mentioned calibration methods, or others as applicable to individual assays which are illustrated from Fig. 2 to Fig. 7 or as per the claims and specifications of the manufacturer.

6.3.2.1 Linear method

6.3.2.2 Point to point method

6.3.2.3 Polynomial method

6.3.2.4 Cubic – Spline method

6.3.2.5 Exponential method

6.3.2.6 4P/5P Logit-log method

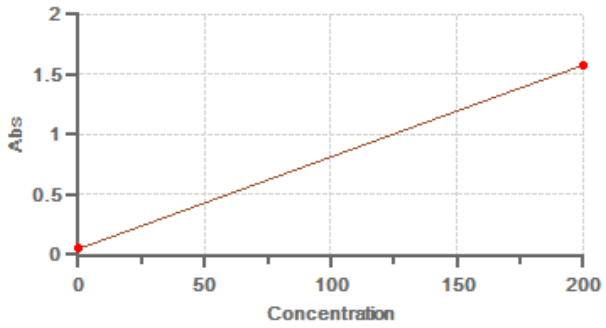


FIG. 2: LINEAR METHOD
(*Clause* 6.3.2.1)

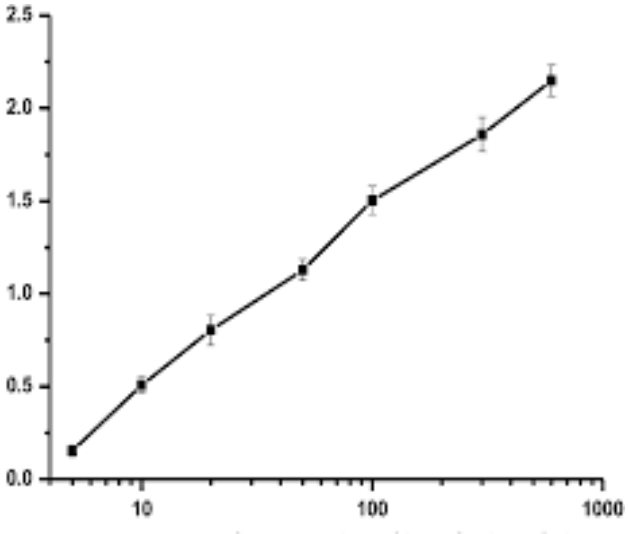


FIG. 3: POINT TO POINT METHOD
(*Clause* 6.3.2.2)

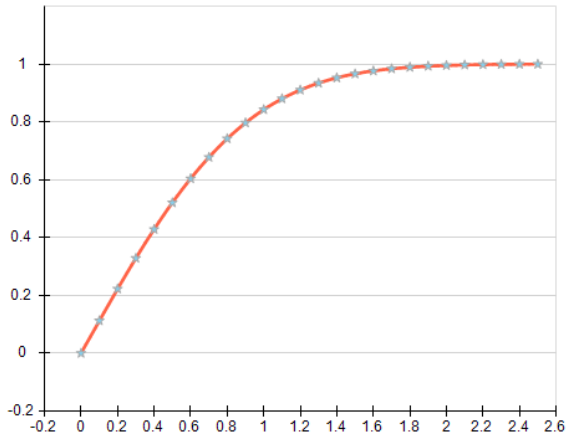


FIG. 4 POLYNOMIAL METHOD
(*Clause* 6.3.2.3)

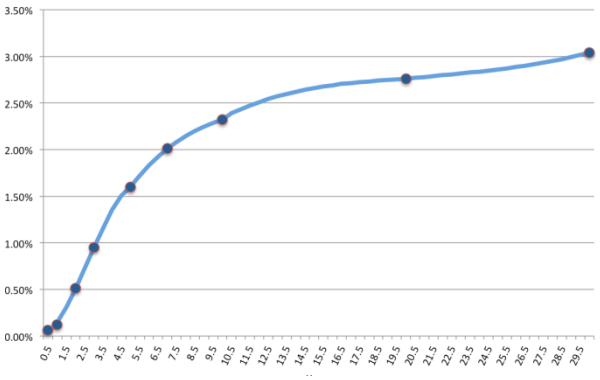


FIG. 5 CUBIC SPLINE METHOD
(*Clause* 6.3.2.4)

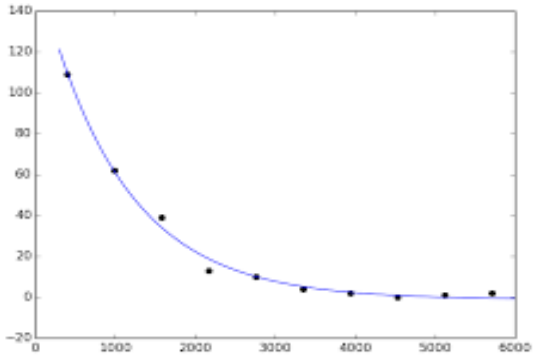


FIG. 6 EXPONENTIAL METHOD
(*Clause* 6.3.2.5)

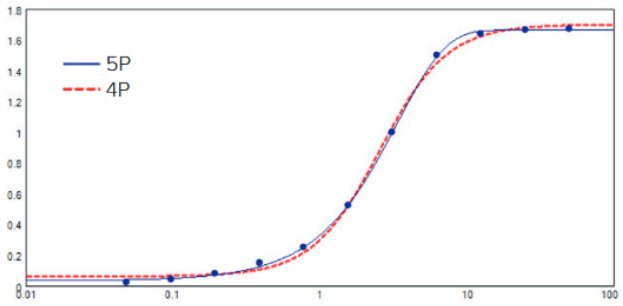


FIG. 7 4P/5P LOGIT-LOG METHOD
(*Clause* 6.3.2.6)

The analyzer should have the provision to estimate results using one or more of the below mentioned methods or additional methods as appropriate or as per the claims and specifications of the manufacturer.

6.3.3.1 1-*point*

This method is used for normal end-point assays using one or two reagents where the final absorbance is used for concentration calculation. Mean of the absorbance's recorded between M_{2Start} (value of absorbance measured immediately after the addition of reagent 2) and M_{2End} (value of absorbance measured at the end of the assay) points are taken and this is used for the calculation of the sample results. This method is illustrated in the following Fig. 8.

6.3.3.2 2-*point*

This method is used for end-point analysis when a sample or reagent blank is necessary. In this assay type, the initial absorbance (usually measured after addition of the first reagent) is recorded and subtracted from the final absorbance (which is usually measured after addition of the second reagent). Necessary correction factors to correct the difference in mixture volume are taken into account while subtracting the initial absorbance. The initial absorbance recorded is the mean of the absorbance's recorded between (value of absorbance measured immediately after the addition of reagent 1) and M_{1End} (value of absorbance measured immediately before the addition of reagent 2) and this absorbance is subtracted from the final absorbance, which is the mean of the absorbance's recorded between M_{2Start} (value of absorbance measured immediately after the addition of reagent 2) and M_{2End} (value of absorbance measured at the end of the assay). This differential absorbance is then used for calculation of sample concentration. This method is illustrated in the following Fig. 9.

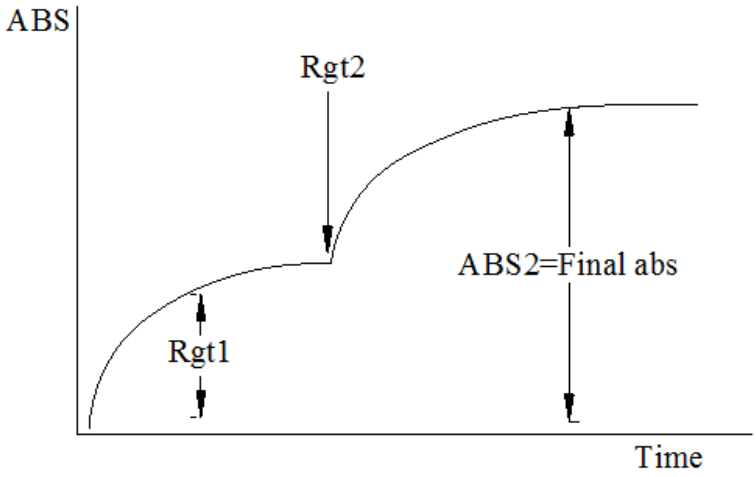


FIG. 8 1-POINT
(*Clause* 6.3.3.1)

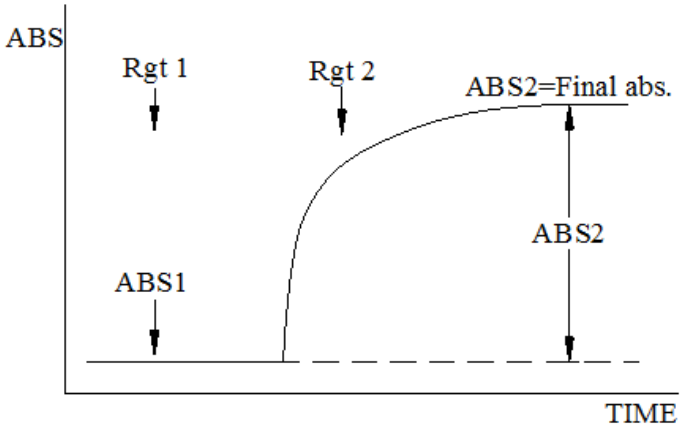


FIG. 9 2-POINT
(*Clause* 6.3.3.2)

6.3.3.3 *Rate-A*

This method is used for kinetic/rate assays where the change in absorbance per minute is used for result calculation. The slope (absorbance change per minute) is obtained from the absorbance recorded between M_{2Start} (value of absorbance measured immediately after the addition of reagent 2) and M_{2End} (value of absorbance measured at the end of the assay) using the least square linear regression method as per the following formula:

$$\frac{\Delta\text{Absorbance}}{\Delta\text{Time}} = \frac{[\sum_{i=1}^{n}(T_i A_i)] - \frac{1}{n}\sum_{i=1}^{n}(T_i)\sum_{i=1}^{n}(A_i)}{\sum_{i=1}^{n}(T^2{}_i) - \frac{1}{n}(\sum_{i=1}^{n}(T_i))^2}$$

Where, T_i is the time in minute and A_i is the absorbance, n is the number of points. This method is illustrated in the following Fig. 10.

6.4 Speed

6.4.1 *Throughput*

The analyzer should give the intended throughput it has been designed for or as as per the claims and specifications of the manufacturer.

6.4.2 Throughput can be determined by theoretical calculations, software simulations, or empirical methods as per the claims and specifications of the manufacturer.

6.5 Quality Control

The analyzer should have the provision to perform and plot QC results with any of the below mentioned features which are illustrated in the Fig. 11 to Fig. 14 or as per the claims and specifications of the manufacturer.

6.5.1 *LJ chart*

6.5.2 *Multi Rules*

6.5.3 *Lab Mean*

6.5.4 Twin plot or other means for comparing the results from multiple controls (stack graph).

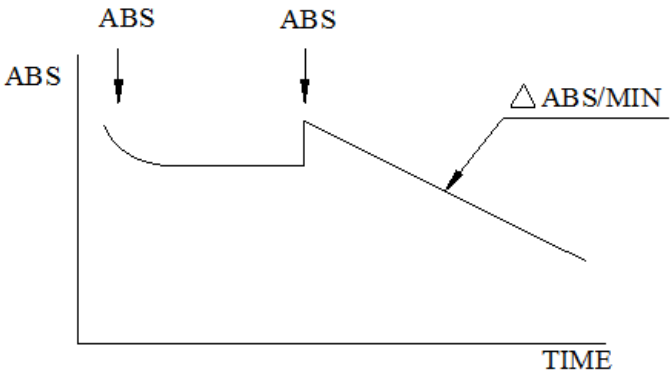


FIG. 10: RATE – A
(*Clause* 6.3.3.3)

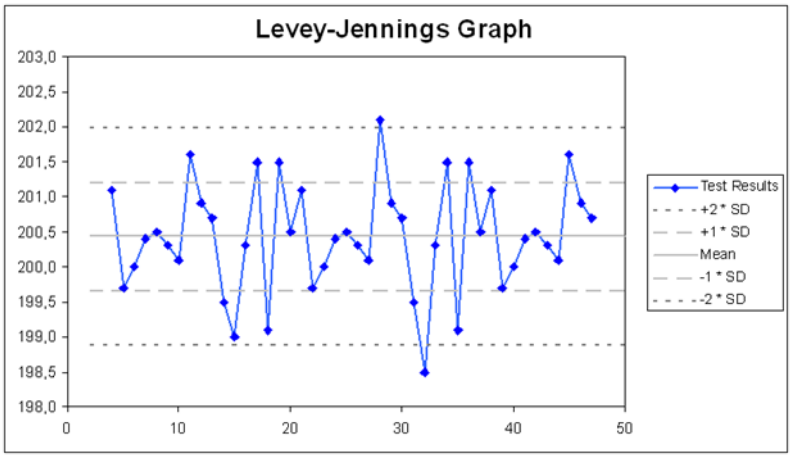


FIG. 11 LJ CHART
(*Clause* 6.5.1)

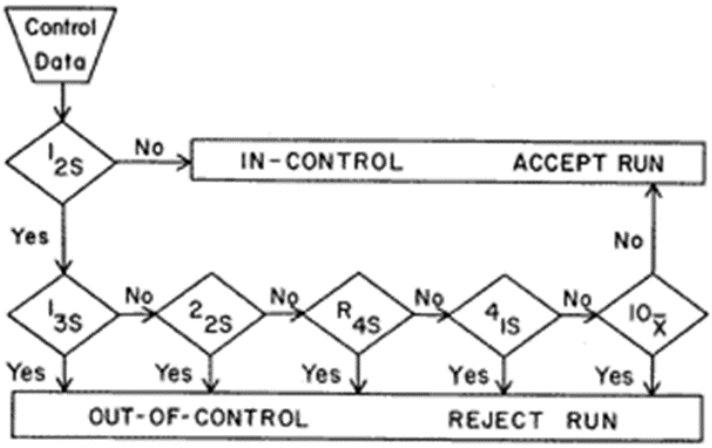


FIG. 12 A) MULTI RULES FLOW CHART
(*Clause* 6.5.2)

QC Rules	Description
1:3S	A single control measurement exceeds +3SD or –3SD limit.
1:2S	A single control measurement exceeds +2SD or –2SD limit.
2:2S	2 consecutive control measurements exceed the same +2SD or –2SD limit.
R:4S	1 control measurement in a group exceeds the mean +2SD and other exceeds –2SD limit.
4:1S	4 consecutive control measurements exceed the same +1SD or –1SD limit.
10X	10 consecutive control measurement fall on one side of the mean.

FIG. 12 B) DESCRIPTION FOR MULTI RULES FLOWCHART
(*Clause* 6.5.2)

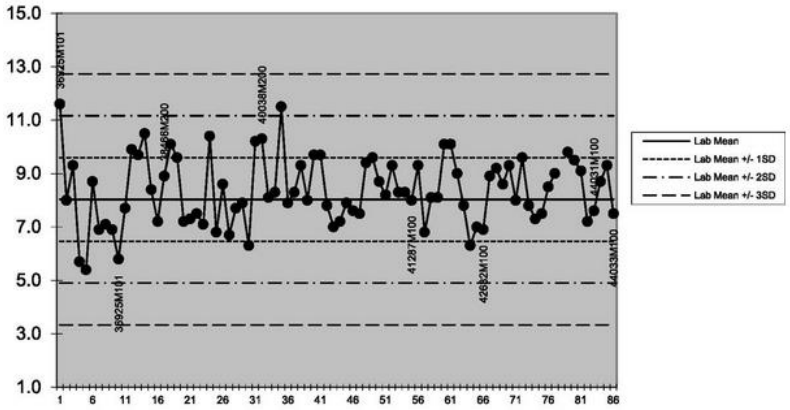
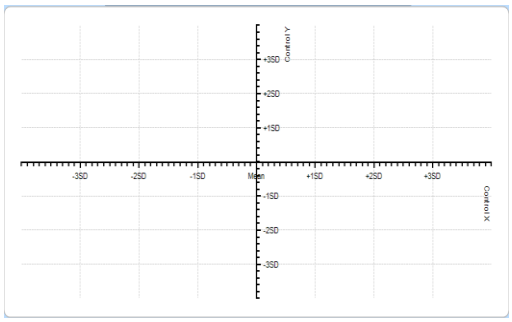
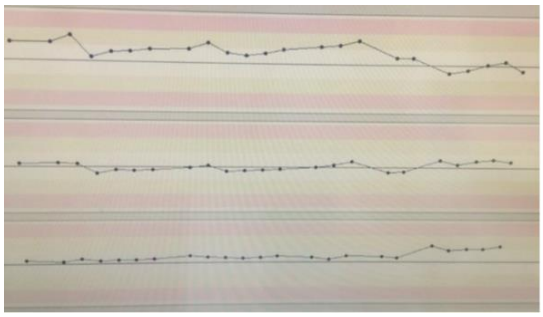


FIG. 13 LAB MEAN
(*Clause* 6.5.3)



Twin Plot



Stack Graph

FIG. 14 TWIN PLOT OR OTHER MEANS FOR COMPARING THE RESULTS FROM MULTIPLE CONTROLS (STACK GRAPH)
(*Clause* 6.5.4)

7 MARKING AND LABELLING

7.1 The following shall be clearly marked on the instrument.

a) Product Name along with the following phrase or symbol "For *in-vitro* Diagnostic use only";
b) Voltage;
c) Storage Temperature – as per manufacturer's recommendations;
d) Batch No./Lot No./Serial No./unique ID;
e) Manufacturer's complete name and address;
f) Marketer's (if any) complete name and address;
g) Manufacturing date;
h) Cautions as applicable; and
j) Relevant symbols.

7.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

8 ACCOMPANYING DOCUMENTS

8.1 Documentation shall comply with the requirements of IS/ISO 14971 and IS/ISO 13485.

8.2 The accompanying documents shall include the following or these documents should be provided to customers during installation:

a) List of accessories; and
b) Instructions for use and maintenance or reference guide.

9 PACKAGING AND TRANSPORTATION

The automated clinical chemistry analyser — Dry type shall comply with the transportation requirements of IS 17724 (Part 2/Sec 101)/ IEC 61010-2-101 and /or any other applicable standard as per manufacturer's specifications.

ANNEX A

LIST OF ABBREVIATIONS

(*Foreword*)

ABS	Absorbance
SD	Standard deviation
CV	Coefficient of variation

ANNEX B

(*Foreword*)

COMMITTEE COMPOSITION

In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee, MHD 19

Organization	*Representative(s)*
E117 first floor Greater Kailash 2, New Delhi, 110048	DR REBA CHABBRA **(*Chairperson*)**
ADMI (Association of Diagnostics Manufacturers of India)	MS VEENA KOHLI
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Agappe Diagnostics Ltd, Kerala	SHRI SREEJITH P. R.
AIIMS Bilaspur	DR ANURAG SANKHYAN
All India Institute of Medical Sciences, New Delhi	DR PROF SARMAN SINGH DR RITU DUGGAL (*Alternate*)
Asia Pacific Medical Technology Association (APACMed), Delhi	SHRI AADITYA VATS
Association Of Indian Medical Device Industry, New Delhi	SHRI ABHIJEET SINGHVI SHRI JATIN MAHAJAN (*Alternate*)
BD India Pvt. Ltd., Gurugram	SHRI GAURAV VERMA SHRI NEERAJ SHARMA (*Alternate*)
BIOMERIEUX, New Delhi	SHRI BIVASH CHAKRABORTY
Bio-Rad Labs India Pvt Ltd, Gurugram	MS DIVYA VOHRA SHRI ALOK KUMAR SONI (*Alternate*)
Boston Scientific India Private Limited, Gurugram	MS KIRTI ARORA MS PREETY SHARMA (*Alternate*)
Central Drugs Standard Control Organization, New Delhi	SHRI SELLA SENTHIL SHRI VINOD KUMAR (*Alternate* I) DR RAVI KANT SHARMA (*Alternate* II)
Central Research Institute, Kasauli	DR ANURAG SANKHYAN DR YASHWANT KUMAR (*Alternate*)
Christian Medical College, Vellore	DR PAMELA CHRISTUDOSS
Directorate General Armed Forces Medical Service, New Delhi	COL AJAY MALIK COL MAHADEVAN KUMAR (*Alternate*)
Directorate General of Health Services, New Delhi	DR INDER PRAKASH
Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	SHRI PRAVEEN KUMAR SHARMA SH PRADEEP KUMAR SAREEN (*Alternate*)
HLL Lifecare Limited, Thiruvananthapuram	SHRI RENJITH M. C. SHRI P. N. GUPTA (*Alternate*)

Organization	*Representative(s)*
ICAR - Indian Veterinary Research Institute, Izzatnagar	DR R. SARAVANAN DR KARUNA DEVI (*Alternate* I) DR ALKA TOMAR (*Alternate* II)
ICMR National Institute of Pathology (NIOP), Delhi	SHRI NASREEN Z EHTESHAM SHRI RUCHI SINGH (*Alternate*)
Indian Council of Medical Research, New Delhi	DR CHANDER SHEKHAR
Indian Institute of Technology Kanpur	DR ASHWANI THAKUR DR ASHOK KUMAR (*Alternate*)
Indian Pharmacopoeia Commission, Ghaziabad	DR RAJEEV SINGH RAGHUVANSHI DR SHATRUNAJAY SHUKLA (*Alternate* I) DR M. KALAIVANI (*Alternate* II)
J Mitra and Company Private Limited, New Delhi	SHRI DIVYA JYOTI CHAWLA SHRI JATIN MAHAJAN (*Alternate*)
Jawahar Lal Institute of Post Graduate Medical Education and Research, Puducherry	DR RAHUL DHODAPKAR DR SUBHASH CHANDRA PARIJA (*Alternate*)
Johnson And Johnson Private Limited, Mumbai	SHRI YATEEN SHAH SHRI NIPUN PATHAK (*Alternate* I) MS AISHWARYA NAIR (*Alternate* II)
Kalam Institute of Health Technology, Visakhapatnam	SHRI DILIP KUMAR CHEKURI DR JITENDAR SHARMA(*Alternate*)
Lady Hardinge Medical College, New Delhi	DR PRITI DR P. LALITA JYOTSNA (*Alternate*)
Maulana Azad Institute of Dental Sciences, New Delhi	DR SANGEETA TALWAR DR MAHESH VERMA (*Alternate*)
Maulana Azad Medical College, New Delhi	DR ROHIT CHAWLA DR C. P. BAVEJA (*Alternate*)
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