भारतीय मानक

Indian Standard

IS 17720 : 2023

इन-विट्रो डायग्नोवटिक (आईवीडी) उपकरणों का प्रदर्शन परीक्षण — स्वचालित ब्लड कल्चर और माइक्रोबियल डिटेक्शन सिस्टम

In-vitro Diagnostic (IVD) Medical Device – Automated Blood Culture and Microbial Detection System

ICS 11.100.10

भारतीय मानक ब्यूरो
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FOREWORD

This Indian Standard was adopted by the 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.

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 M47	Principles and procedures for blood cultures, 1st edition
EN 13612	Performance evaluation of in vitro diagnostic medical devices
EN 13641	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
ISO 18113-2:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostics reagents for professional use

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

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 shall be the same as that of the specified value in this standard.

Indian Standard

IN-VITRO DIAGNOSTIC (IVD) MEDICAL DEVICE — AUTOMATED BLOOD CULTURE AND MICROBIAL DETECTION SYSTEM

1 SCOPE

This standard covers the requirements of device used for diagnosing bloodstream infections (BSIs) by detecting the growth of microorganisms in the blood culture.

2 REFERENCES

The standard 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 the standard are encouraged to investigate the possibility of applying the most recent edition of these standards:

IS No.	*Title*
IS 17724	Safety requirements for electrical equipment for measurement, control, and laboratory use:
(Part 1) : 2023	General requirements
(Part 3) : 2023	Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
(Part 4) : 2023	Particular requirements for *In-vitro* diagnostic IVD medical equipment
IS/ISO 13485 : 2016	Medical devices — Quality management systems — Requirements for regulatory purposes (*first revision*)
IS/ISO 14971 : 2019	Medical devices — Application of risk management to medical devices
IS/ISO 15190 : 2003	Medical Laboratories — Requirements for Safety
IS/ISO 23640 : 2011	*In vitro* diagnostic medical devices — Evaluation of stability of *in vitro* diagnostic reagents

3 DESIGN REQUIREMENTS

3.1 The device is designed for detection of bacteria and fungi in clinical specimens, blood and blood products. Samples are drawn from patients or bagged blood/blood products and injected directly in to culture vials, which are placed into the device for incubation and testing.

3.2 It is an automated system for detecting the presence of microorganisms in clinical samples. Inoculated samples are placed in the device. Samples in protocol are monitored for microbial activity over time by measuring the consumption and production of any gases such as CO_2, H_2, N_2 and O_2 by microbial metabolism.

3.3 The user interface subsystem shall encompass all functions pertaining to device workflow from inserting samples into the instrument for testing and subsequent removal of positive and final negative samples.

4 PRINCIPLE

When microorganisms are present in culture receptacles, they metabolize nutrients in the culture medium, attributing to gas consumption and/or gas production. Specific device algorithms should be in place to detect and declare the positive samples. The system should be able to perform a self-diagnosis at specified time period and run a test cycle.

5 ENVIRONMENTAL REQUIREMENTS

5.1 The system should be operable at temperature range of 15 ºC to 28 ºC and humidity of the range 10 percent to 90 percent RH and non-condensing.

6 INTERPRETATION OF RESULT

6.1 The algorithms shall be applied after the readings are taken.

6.2 Algorithms shall determine whether the culture contains evidence of microbial growth.

6.3 The instrument shall be means of algorithms determine positive events after loading into the blood culture system.

7 INDICATION OF RESULT

7.1 Positive cultures upon detection shall be flagged by the following means:

a) Visual alarm or Indicator lights; and
b) Audible alarm.

8 MEDIA REQUIREMENTS

8.1 The medial components shall comply with the manufacturer's specification.

8.2 The media can be of various types aerobic, anaerobic, or pediatric bottle.

9 MEDIA LABELS

9.1 All vials and bottles shall have barcode labels affixed at manufacture.

9.2 The label shall contain a unique sequence number which includes the medium type.

9.3 Disposal of empty vials/reagents after testing shall be as per the requirements IS/ISO 15190.

10 INOCULATION VOLUME AND BLOOD VOLUME

10.1 Inoculation volume vary with medium type. The volume of blood is critical. The number of organisms per mL of blood in most cases of bacteremia is low, especially if patient is on antimicrobial therapy.

10.2 In infants and children, the number of organisms per mL of blood in most cases of bacteremia is higher than adults.

10.3 The recommended blood volume shall be as follows.

10.3.1 For children, the optimum blood volume shall be based on the patient weight as published in CLSI M47 Principles and Procedures for Blood Cultures.

10.3.2 For adult, the optimum blood volume shall be up to 10 mL blood per bottle.

11 PERFORMANCE EVALUATION

11.1 The system should free from scratches.

11.2 The symbols and characters shall be legible.

11.3 The fastening pieces shall be connected firmly and shall be free from loosening.

11.4 There should have barcode identification.

11.5 Positive vials/bottles are indicated immediately by the indicator light on the front of the system, accompanied with an audible alarm.

11.6 Negative results are indicated by bottle status indicator and system indicator.

11.7 The system shall give alarm for detection of positive vial or bottle and temperature.

11.8 Reproducibility of Positive Culture Results

When the media bottles are inoculated with the standard strains (as per manufacturer specification), it should be positive within the timeframe recommended for the media bottles.

11.9 Performance should be documented as technical documentation as per EN 13612, Performance evaluation of *in vitro* diagnostic medical devices.

11.10 The stability of the reagent shall be evaluated as per IS/ISO 23640.

12 SAFETY REQUIREMENTS

12.1 The automated blood culture and microbial detection system shall comply with the electrical safety requirements for measurement, control, and laboratory device as per IS 17724 (Part 1), IS 17724 (Part 3) and IS 17724 (Part 4).

12.2 The automated blood culture and microbial detection system shall comply with processes identified as per EN 13641.

13 REPORT

13.1 The system shall have the provision for generating the following reports but not limited to the same:

a) Load report,
b) Status report,
c) Current Inventory,
d) Current negatives,
e) Current positives,
f) Loaded vials/bottles,
g) Calibration report,
h) Calibration history report,
j) Unloaded negative vials/bottles,
k) Unloaded positive vials/bottles, and
m) Unloaded vials/bottles.

14 MARKING AND LABELLING

14.1 The following shall be clearly and permanently marked on the instrument.

14.1.1 Product name along with the following phrase **"For *in- vitro* Diagnostic use only"**.

14.1.2 The number of this Indian Standard.

14.1.3 The name of the manufacturer or supplier, model number and date of manufacture/serial number.

14.1.4 The system shall comply with the labelling requirements of ISO 18113-2.

14.2 BIS Certification Marking

14.2.1 The system may also be marked with a Standard Mark.

14.2.2 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.

15 DOCUMENTATION

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

15.2 The accompanying documents shall include the following:

15.2.1 Instructions for use

15.2.2 Instructions for maintenance and troubleshooting.

16 TRANSPORTATION REQUIREMENTS

16.1 The system shall comply with the Transportation requirements of IS 17724 (Part 4).

ANNEX A

(*Foreword*)

COMMITTEE COMPOSITION

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

Organization	*Representative(s)*
In Personal Capacity (*E117 first floor Greater Kailash 2, New Delhi, 110048*)	DR REBA CHABBRA **(*Chairperson*)**
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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*)
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Review of Indian Standards

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