BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT

AGENDA

Technical Committee	*Meeting No*	*Date & Time*
In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices Technical Committee, MHD 19	17th	27 September 2024 2: 00 PM
Virtual Meeting (Webex platform) **Meeting Link**: https://bismanak.webex.com/bismanak/j.php?MTID=mcf371dded245580bd990a8641c0c21ad **Meeting number**: 25120162964 **Password**: 2VPn8MMgvi7		
Chairperson Dr. Reba Chhabra In Personal Capacity CCAMP, Bengaluru	**Member Secretary** Nagavarshini M., Scientist C/ Deputy Director, Bureau of Indian Standards	

ITEM 0 GENERAL

0.1 WELCOME ADDRESS BY BIS

0.2 OPENING REMARKS BY CHAIRPERSON

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The Minutes of 16th Meeting of *In-vitro* Diagnostic Medical Devices and Biological Evaluation of Medical Devices Technical Committee, MHD 19 held on 21 June 2024 was circulated to all members through BIS Portal vide letter no: MHD 19/ A 2.16/ Minutes dated 19 July 2024.

Comments received on the minutes from Mr Asok Kumar, Abbott India, with regards to IS of Electrolyte analyser has been is detailed in ITEM 10.1.

The Committee may deliberate and formally confirm the minutes.

ITEM 2 SCOPE AND COMPOSITION OF COMMITTEE

2.1 The present scope of In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee (MHD 19) is as follows.

Scope: To formulate Indian Standards on:

a) *In-vitro* Diagnostic kits, reagents, analyzers and associated software;

b) Biological and clinical evaluation of medical and dental materials, devices, implants together with standardization of biological test methods applicable to those materials and devices;

c) Good clinical practice principles to clinical investigations in humans of those devices; and

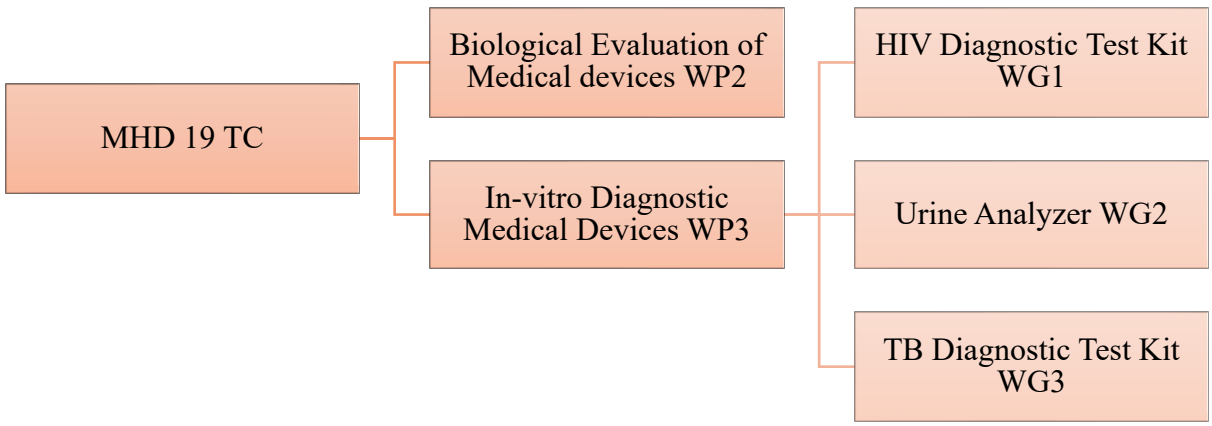
d) To co-ordinate with the work of:

1) ISO/TC 194 - Biological and clinical evaluation of medical devices, P Member
2) ISO/TC 212/WG 3 In-vitro diagnostic products, and P Member
3) ISO/TC 212/WG 4 Microbiology and molecular diagnostics. P Member

Committee may note.

2.2 The present composition of the MHD 19 committee is as given in the Link.

2.3 The Structure of the Committee is as follows



2.4 Revised nominations have been received from the following organization

S. No.	*Name & Organization*
1	National Institute of Biologicals, Noida

2.5 Co-option request has been received from the following organizations

S. No.	*Name & Organization*
1	Dr. Suresh Thakur, President - Scientific Affairs, Trivitron Healthcare
2	Bio-Rad Laboratories (India) Pvt Ltd, Gurugram
3	Mr. Anil Kumar Madupu, Baxter Innovations and Business solutions, Bangalore

Committee may deliberate.

ITEM 3 DRAFT STANDARDS UNDER PRINT

3.1 The following drafts Indian Standards are under print

S. No.	*Document Number*
1.	MHD/19/15611 In-vitro Diagnostic (IVD) Devices - Blood Gas Analyzers

Committee may note.

ITEM 4 DRAFT UNDER PREPARATION

The following new subjects have been taken up for standardization.

S. No.	*Subject*
1.	HIV Diagnostic Kit – Circulated to NIB & ICMR for comments
2.	TB Diagnostic Kit – Working group constituted, WG meeting to be scheduled, after the expert members have been co-opted
3.	Urine Analyzer - Working group constituted, WG meeting to be scheduled, after the expert members have been co-opted
4.	Blood cell counter
5.	Blood coagulation analyzer
6.	Haemoglobin analyzer

Committee may discuss and decide on the further course of action for the subjects.

ITEM 5 NEW SUBJECTS – DGHS PRIORITY LIST

5.1 The following 25 subjects have been received from DGHS for formulating Indian Standard.

1.	Biochemistry	HPLC HbA1c analyser
2.	Haematology	HPLC hemoglobinopathies analyser
3.	Haematology	Automated ESR Analyser
4.	Haematology	Platelet Aggregometer
5.	Haematology	Platelet function testing system
6.	Haematology	CBC Counter
7.	Haematology	Automated Haematology Analyser
8.	Haematology	Automated coagulation analyser (Fully automated & semi-automated)
9.	Histology	Tissue embedding station/Automated Rotary microtome
10.	Histology	Quick cool histology
11.	Histology	Automatic Tissue Processor
12.	Histology	Cryomicrotome
13.	Histology	Tissue microarray System
14.	Histology	Fully Automated Immunostainer
15.	Immunology	Fully Automated Indirect Immunofluorescence IIF assay analyser for ANA Screening
16.	Immunology	Chemiluminescence Analyser
17.	Immunology	Fully Automated Chemiluminescence immunoassay analyser (CLIA)
18.	Immunology	Microarray/ similar technology for rapid syndrome management
19.	Microbiology	Cartridge-Based Nucleic Acid Amplification Test
20.	Molecular Biology	Fully Automated high risk HPV DNA detection & genotyping system
21.	Pathology	Automated Urine and fluid Analyser
22.	Pathology	Urine Strip Analyzer
23.	Pathology	Electrophoresis system
24.	Pathology	Western blot apparatus
25.	RM	Automated semen Analyser

Committee may deliberate and decide the further course of action.

ITEM 6 NWIPs RECEIVED

6.1 The following proposals have been received from Accurex Biomedical and was circulated to members for comments

Proposed Title: Test Method for Performance evaluation of In-vitro Diagnostics IVD Reagent Kit for the detection of

i) **Adenosine Deaminase (ADA)** (Liquid Stable Clinical Chemistry Reagents Kits)
ii) **Homocysteine** (Liquid Stable Clinical Chemistry Reagents Kits)

iii) **HbA1c** (Liquid Stable Clinical Chemistry Reagents Kits)
iv) **Lipase** (Liquid Stable Clinical Chemistry Reagents Kits)
v) **Low-Density Lipoprotein LDL Cholesterol** (Liquid Stable Clinical Chemistry Reagents Kits)
vi) **Triglyceride** (Liquid Stable Clinical Chemistry Reagents Kits)

S. No.	*Commenter*	*Comment*
1.	Mr. P S Chandranand, CCAMP	Document
2.	Mr. Asok Kumar, Abbott	Document

Committee may deliberate and decide on whether the subjects can be taken up for standardization.

6.2 Mr. P S Chandranand, CCAMP has proposed to have a "**Code of practice standard for Instructions for Use (IFU) / Kit Insert of IVD Reagent Kit."** The sections proposed are as follows

i. Product identification
ii. Intended use statement
iii. Statement that the product is for in-vitro diagnostic use
iv. Test principle summary and explanation
v. Warnings and precautions
vi. Materials provided (test device, reagents, calibrators, controls and accessories)
vii. Materials required but not provided
viii. Instrumentation needed but not provided (if applicable)
ix. Troubleshooting
x. Collecting, preparing specimens and disposal, including storage (if applicable)
xi. IVD storage, operating conditions and stability
xii. Test procedure
xiii. Reading test results
xiv. Interpretation of test results
xv. Limitations of the procedure
xvi. Performance characteristics (Measuring Range/ LoD, Analytical sensitivity and specificity, Accuracy, Precision)
xvii. List of references
xviii. Contact information
xix. Document control
xx. Symbol key
xxi. Definition of terms and abbreviations (if required)

Committee may deliberate and decide on whether the subject can be taken up for standardization.

ITEM 7 COMMENTS ON PUBLISHED STANDARDS

7.1 There are no comments received on the published standards.

7.2 Comments on published standards can be submitted in the following link.

ITEM 8 INTERNATIONAL ACTIVITIES

8.1 MHD 19 has liaison with ISO TC 194 and ISO TC 212 WG 3 and WG 4.

ITEM 9 PROGRAM OF WORK

9.1 The Present Program of Work of MHD 19 is given at Link.

ITEM 10 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

10.1 Presentation by Mr. Asok Kumar, Abbott, apprising the technical justification on why IS 17721: 2024 may be applicable for only indirect method, and that how the requirements mentioned may not be applicable for other technologies like direct and solid state analyser.

Committee may deliberate and decide.

ITEM 11 ANNUAL MEETING CALENDAR

11.1 The Next meeting (18th) of MHD 19 is scheduled on 20 December 2024 as per AMC.

Committee may note.

ITEM 12 ANY OTHER BUSINESS