



# ***e-Newsletter***

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***Materiovigilance Programme of India***

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# Avoid Hazard ➡ Follow the Plan

## *Risk Management Process Overview*

01

**Hazards  
Identification**



- Hazard category
- Foreseeable sequence of events
- Hazardous situation
- Harm

02

**Risk  
Evaluation**



- Severity
- Likelihood
- Risk Level

03

**Risk  
Control**



- Benefits
- Immediate Recipients
- Means to be used

04

**Residual  
Risk  
Definition**



- Corrective Action/Preventive Action
- Control Measures
- Re-evaluation

05

**Report  
&  
Statistics**



- Review
- Summary
- Chart



# T Training & Education



## *Management and Ensuring Safety of Medical Devices*

Two day training programme on “Management and Ensuring Safety of Medical Devices” was organized on June 22, 2019 at Coimbatore, Tamilnadu by Royal Care Super Speciality Hospital to sensitize the healthcare professionals, manufacturers, importers & distributors of medical devices including all other stakeholders for better understanding of management and safety of medical devices and also for promoting patient well-being, strengthening of materiovigilance system and to aware stakeholders about the necessity and importance of medical devices adverse events (MDAE) reporting.

The training programme was graced by the esteemed presence of Mrs. Shanthi Gunasekaran, Dr. V. Kalaiselvan, Mr. Ajay Basil, Dr. S. Ramalingam, Dr. K. Madeswaran and Mr. D. Gandhi Raj.

More than 30 professionals from different organizations participated in the training programme.

22 JUNE, 2019

# M

## edical Devices testing laboratory (MDTL) for carry out test or evaluation of medical device

IVDs for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus, Blood Grouping sera, Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent.

Surgical Dressings, Surgical Cotton, Surgical Bandages, Disinfectant

Intra Uterine Devices (IUD) and Falope Rings





## List of Laboratories to be considered for conducting Performance Evaluation of In-Vitro Diagnostics

### In -Vitro Diagnostics for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus

- **National Institute of Biologicals** : Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309
- **National AIDS Research Institute (ICMR)** : 73, 'G'-Block, MIDC, Bhosari, Pune - 411026, Maharashtra, India
- **National Institute of Virology** : 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India
- **Christian Medical College & Hospital** : Ida Scudder Road, Vellore, Tamil Nadu 632004
- **Department of Clinical Virology, Institute of Liver & Biliary Sciences** : D-1, Vasant Kunj New Delhi-70

- **National Institute of Biologicals** : Plot No. A-32, Sect.62, Institutional Area, Noida, Uttar Pradesh 201309
- **Indian Red Cross Society** : 1, Red Cross Road, New Delhi`

### In vitro Diagnostic Medical Devices for Blood Grouping or Tissue Typing

### Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent

- **National Institute of Biologicals** : Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309

- **Institute of Cytology and Preventive Oncology (ICPO)** : I-7, Sector - 39, Noida 201301 Uttar Pradesh, INDIA
- **Chittaranjan National Cancer Institute** : 37, S.P. Mukherjee Road, Kolkata-700 026.INDIA
- **Tata Memorial Hospital** : Dr.E Borges Rd. Parel, Mumbai- 400012
- **Tata Medical Center** : 14 MAR (E-W), New Town, Rajarhat, Kolkata 700156
- **Calcutta Medical College** : Dept. of Oncology/Medical Oncology 88, College St., College Square, Kolkata, West Bengal 700073

### Reagents/Kits for detection of Cancer

### Reagents/ Kits for Detection of Tuberculosis (TB)

- **NIRT** : Mayor Sathiyamoorthy Rd., Chetpet, Chennai – 600031
- **NTI** : AVALON" No.8, Bellary Road, Bangalore 560 003
- **PGIMER** : Sector 12, Chandigarh, 160012
- **NITRD** : Sri Aurobindo Marg, Nr. Qutub Minar, New Delhi- 110030
- **National Jalma Institute of Leprosy & other mycobacterial diseases** : P.O BOX 101, Dr. M.Miyazaki Marg, Agra – 282001
- **SDS TRC & RGICD** : Someshwara Nagar, Bangalore - 560 029
- **Rajan Babu T.B. Hospital** : Kingsway Camp, GTB Nagar, Delhi - 110009

- **National Institute of Malaria Research (ICMR)** : Sector 8, Dwarka, Delhi-110077 (India)
- **National Institute for Research in Tribal Health** : Nagpur Rd. Near NSCB Medical Cooled Jabalpur, Madhya Pradesh, 482003.
- **National Institute of Cholera and Enteric Diseases** : P-33, C.I.T. Road, Scheme XM, Belegghata, Kolkata 700010
- **All India Institute of Medical Sciences** : Division of Clinical Microbiology & Molecular Medicine New Delhi-110029
- **National Institute of Communicable Diseases (NICD)** : 22, Sham Nath Marg, New Delhi

### Reagents/ Kits for Detection of Malaria

### Reagents/Kits for Detection of Dengue

- **National Centre for Disease Control** : 22, Sham Nath Marg, New Delhi-110 054, India
- **National Institute of Virology** : 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001
- **Department of Clinical Virology, Institute of Liver & Biliary Sciences** : D-1, Vasant Kunj New Delhi-70
- **National Institute of Biologicals**, Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309
- **Christian Medical College & Hospital** : Ida Scudder Road, Vellore, Tamil Nadu 632004

- **Any Central Government or State Government Laboratory of any hospital or of any institute.**

### Reagents/ Kits for Detection of Chikungunya



### Reagents/ Kits for Detection of *Treponema pallidum* (Syphilis)

- **National Institute of Biologicals** : Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309
- **Christian Medical College & Hospital** : Ida Scudder Road, Vellore, Tamil Nadu 632004

- **Dept. of Microbiology, The Postgraduate Institute of Medical Education and Research** : Chandigarh, Sector 12, Chandigarh, 160012
- **Division Bacteriology, ICMR-National Institute of Cholera and Enteric Diseases** : P-33 C.I.T. Road, Kolkata-700010

### Reagents/Kits for Detection of Typhoid

### Reagents/Kits for Detection of Influenza

- **Department of Clinical Virology, Institute of Liver & Biliary Sciences** : D-1, Vasant Kunj New Delhi-70
- **National Institute of Virology** : 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune - 411001, India
- **Division Bacteriology, ICMR-National Institute of Cholera and Enteric Diseases** : P-33 C.I.T. Road, Kolkata-700010

- **Any Central Government or State Government Laboratory of any hospital or of any institute.**

**Reagents/Kits for Detection of ToRCH, markers for Congenital disorders, sexually, transmitted Disease, Human Papilloma Virus infection, Detection of autoimmune disorders, human Genetic testing**



### *Field safety corrective action notification*



SenTec has become aware of an issue associated with Membrane Changers and their Inserts. SenTec decided to initiate a correction and to replace Membrane Changers (MC-R) and Membrane Changer Insert (MC-I) containing cartridges of LOT4U000114 in the field. Accessories / Associated Devices Affected: MC-I, MC-R, MC-SET, SSET, SSET\_nG, SSET-N, SSET-N\_nG

### *On end-customer level*

- 1** Follow detailed instructions according to notice RF-009899 provided by SenTec
- 2** Be aware of possible issue during membrane change and inspect sensor carefully before & after use (as per SenTec's Instruction Manual)
- 3** If air bubbles are detected below the membrane change sensor membrane according to instructions for use
- 4** If sensor is getting slow, displaying sensor problem 10, 11 or 12, or showing signs of dried out electrolyte/unusual drift, change sensor membrane
- 5** Contact : [millenniumbiotech@rediffmail.com](mailto:millenniumbiotech@rediffmail.com) for replacement and further instructions. Return affected lot numbers as soon as replacement arrives.



*Did you know?*

"Medical Device Adverse Event Reporting Form  
is now available in editable version"

**CLICK HERE**

**CLICK HERE**

**Helpline : 1800 180 3024**

**Indian Pharmacopoeia Commission**

Ministry of Health & Family Welfare  
Government of India

Sector-23, Raj Nagar, Ghaziabad - 201002

Tel. : 0120-2783400, 2783401, 2783392

Fax : 0120-2783311

**For any other Information/Suggestion  
Query Contact:**

Materiovigilance Programme of India

Email : [lab.ipc@gov.in](mailto:lab.ipc@gov.in),

[mvpi.ipcindia@gmail.com](mailto:mvpi.ipcindia@gmail.com)

Website : [www.ipc.gov.in](http://www.ipc.gov.in)

*We have started a journey of Materiovigilance, for saving lives*