



Our Ref : (23) dlm. MDA. 100-1/7/2

Date : 2 Oktober 2017

**CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 4 YEAR 2017**

**POLICY ON IMPLEMENTATION AND ENFORCEMENT UNDER THE MEDICAL
DEVICE ACT 2012 (ACT 737):**

**RECOGNITION OF INSTITUTE FOR MEDICAL RESEARCH (IMR) TO PROVIDE
THE REPORT OR DATA OF CLINICAL EVIDENCE OR PERFORMANCE
EVALUATION FOR THE PURPOSE OF CONFORMITY ASSESSMENT BY
CONFORMITY ASSESSMENT BODY**

PURPOSE

1) The purpose of this circular is to set the policy for implementation and enforcement under the Medical Device Act 2012 (Act 737) relating to the recognition of Institute for Medical Research (IMR) as one of the institutions or laboratories which is capable of carrying out and providing data or report of clinical evidence or performance evaluation of medical device. This further data or report may be used for conformity assessment by Conformity Assessment Bodies for the purpose of medical device registration.

BACKGROUND

2) Regulation 4(1) of Medical Device Regulation 2012, all medical device shall be subjected to conformity assessment to demonstrate its conformity to the requirement of medical device law.

3) Regulation 4(2) requires the manufacturer to collect all evidence of conformity and, depending on the class of a medical device, shall appoint a conformity assessment body registered by Authority under Section 10 of the Act to conduct the assessment on the conformity.

4) Regulations 4(3) requires, upon completion of the conformity assessment, and if the conformity assessment body is satisfied that all the requirements have been fulfilled, the conformity assessment body shall issue a report and certificate of conformity to the establishment.

5) In accordance with Clause 5(1) in Third Schedule (Conformity Assessment Procedure) of the Medical Devices Regulation 2012, conformity assessment for the purpose of registration of a medical device shall comprise of the following elements:

- (a) conformity assessment on quality management system;
- (b) conformity assessment on post-market surveillance system;
- (c) conformity assessment on technical documentation; and
- (d) declaration of conformity

6) One of the conformity assessment for the purpose of medical device registration is the conformity assessment of technical documentation. The manufacturer shall collect and examine evidence and undertake procedures to determine conformity of a medical device to essential principles of safety and performance. One of the essential principles of safety and performance is data or report of clinical evidence / performance evaluation to be obtained to support the performance evaluation of medical device.

7) Currently, there is no conformity assessment provided by Conformity Assessment Body especially on medical devices that detect infectious diseases such as screening dengue and malaria infections (eg IVD test kit: Dengue Ab detection kits, Malaria kits, etc.)

8) Technical personnel conducting assessment on IVD medical devices is also inadequate and the assessment has to be sent abroad. This causes the conformity assessment of the medical device to take a long time and indirectly delay the registration process of the medical device. At the same time, the cost of conducting overseas assessments is rather high.

9) This recognition is one of the initiatives to help the establishment to reduce cost and time to gather clinical evidence or performance evaluation of medical devices compared to overseas.

10) This approach will also facilitate the local institutions or laboratories in its development, financial growth and recognition not only in Malaysia, but also globally.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

11) **The Medical Device Authority Meeting No. 4/2016 has decided to recognize the Institute for Medical Research (IMR) as one of the institutions or laboratories which is capable of carrying out and provide data or report of clinical evidence or performance evaluation for conformity assessment by Conformity Assessment Bodies for the purpose of medical device registration. List of testing or assessment is as per Attachment A.**

USAGE AND EFFECTIVE DATE

12) Circular issued shall be used as part of requirements under Act 737 and this circular shall be effective from the date it is issued.


ENQUIRIES

13) Any enquiries relating to this circular can be forwarded to:

Chief Executive
Medical Device Authority
Ministry of Health Malaysia
Level 5, Menara Prisma, No. 26
Jalan Persiaran Perdana, Presint 3
62675 Putrajaya, MALAYSIA
Tel. : (+603) 8892 2400, Fax: (+603) 8892 2500
Email: mdb@mdb.gov.my

Thank you.

"BERKHIDMAT UNTUK NEGARA"



(YBHG. DATUK DR NOOR HISHAM BIN ABDULLAH)
Chairman
Medical Device Authority
Ministry of Health Malaysia

ATTACHMENT A

SENARAI UJIAN YANG BOLEH DIJALANKAN EVALUASI OLEH IMR

PUSAT PENYELIDIKAN ALERGI DAN IMMUNOLOGI

NO.	UJIAN
1	Anti-nuclear antibody (ANA)
1	Total IgE Test
2	Specific IgE Test
3	Tryptase
4	Eosinophil cationic protein (ECP)
5	ENA screening
6	Anti-Sm antibodies
7	Anti-U1RNP antibodies
8	Anti-SSA/Ro antibodies
9	Anti-SSB/La antibodies
10	Anti-Sc1-70 antibodies
11	Anti-Jo-1 antibodies
12	Anti-Centromere antibodies
13	Anti-smooth muscle antibody
14	Anti-mitochondrial antibodies
15	Anti-gastric parietal cell antibodies
16	Anti-liver-kidney microsomal
17	P- and C-ANCA
18	Myeloperoxidase (MPO)
19	Proteinase 3 (PR3)
20	Anti-cardiolipin antibodies
21	Acetylcholine receptor antibodies
22	Coeliac antibodies (Anti-gliadin, Anti-tTG, Anti-endomysial)
23	Skin antibodies: Anti-BP 180, Anti-BP 230
24	Skin antibodies: Anti-desmoglein 1,3
25	Diabetes antibodies: Anti- Anti- Glutamic acid decarboxylase (GAD)
26	Diabetes antibodies: Anti-islet cells (ICA)
27	Diabetes antibodies: Anti-insulin

28	Diabetes antibodies: Anti-insulinoma associated antigen 2 (IA2)
29	Anti-glomerular basement membrane
30	Paraneoplastic Neurological Syndrome (PNS) antibodies
31	Specific liver antibodies
32	Anti-Cyclic Citrullinated Peptides (CCP)
33	Anti-aquaporin 4
34	Anti-N-Methyl-D-Aspartate Receptor (NMDR)
35	Anti-ganglioside antibodies
36	Anti-β2-Glycoprotein antibodies (IgG, IgM)
37	T and B cells enumeration by flow cytometry
38	Immunoglobulin A
39	Immunoglobulin M
40	Immunoglobulin G
41	Complement C3
42	Complement C4
43	HLA Typing Class I & II (A, B & DR)
44	HLA Typing Class I (Loci A, B, C)- low to medium resolution
45	HLA Typing Class II (Loci DR, DQ)- low to medium resolution
46	HLA Typing Class I (Loci A, B, C) - per locus
47	HLA Typing Class II (Loci DR, DQ) - per locus
48	HLA Typing Class I (Loci A, B, C)- high resolution
49	HLA Typing Class II (Loci DR, DQ)-high resolution
50	HLA Crossmatch (CDC)
51	HLA Crossmatch (FLOWCYTOMETRY)
52	HLA Antibody (PRA)
53	HLA Antibody (DSA)
54	Anti-PLA 2R
55	Anti-RA 33

PUSAT DIAGNOSTIK KHAS

UJIAN	
NO.	
1	Fragile-X Syndrome
2	Spinal Muscular Atrophy (SMA)
3	Prader Willi/Angelman Syndrome
4	Mitochondrial DNA deletion/specific mutations
5	Quantitation of specific proteins
6	Quantitation of kappa & lambda free light chain
7	Quantitation of total protein (serum or urine or CSF)
8	Serum protein electrophoresis and immunofixation
9	Urine protein electrophoresis and immunofixation
10	CSF and serum oligoclonal band
11	Alpha-1-Antitrypsin protein profiling
12	CDG-Transferin protein profiling

PUSAT PENELITIAN PENYAKIT BERJANGKIT

UJIAN	
NO.	
1	Identification of aerobic bacteria
2	Identification of anaerobes
3	Antibiotic susceptibility for aerobes (Etest plus disc diffusion)
4	Fungal culture
5	Identification of fungus
6	Fungal test medium
7	Antifungal susceptibility testing
8	Typhus serology
9	Meloidosis serology
10	Brucellosis IgM & IgG
11	Brucellacapt total Ig for brucellosis
12	Lyme's disease serology screening

13	Lyme's disease confirmatory (western blot) IgM & IgG
14	Q Fever - serology
15	Cat scratch disease - serology
16	PCR and identification of Burkholderia pseudomallei
17	PCR, sequencing and biochip test for detection and identification of fungus
18	Pneumocystis jirovecii - Indirect immunofluorescence test
19	Leptospirosis - MAT
20	Leptospira PCR
21	Leptospirosis ELISA
22	Leptospirosis latex/lateral flow
23	Tuberculosis - PCR
24	Bordetella pertussis - PCR
25	Brucellosis - PCR
26	Other Bacterial pathogens PCR
27	Histoplasma and P. marneffei Real time PCR
28	Salmonella (non-human) - Serotyping
29	Bacterial ID
30	Aspergillus Galatomanan
31	Dengue Antibody Rapid test kit
32	Dengue NS1 Antigen Rapid test kit
33	Dengue Combo kit
34	Dengue IgG ELISA
35	Dengue IGM ELISA
36	Dengue NS1 ELISA
37	HIV Ab Rapid test
38	HIV Ab ELISA
39	Flu A and Flu B Real Time RT-PCR
40	Dengue Multiplex Real Time RT-PCR (4 targets)
41	Hepatitis B surface antigen ELISA
42	Hepatitis B surface antigen Rapid

PUSAT PENELITIAN KARDIOVASKULAR, DIABETES DAN PEMAKANAN

NO.	UJIAN
1	Thyroglobulin
2	INSULIN-LIKE GROWTH FACTOR 1
3	17-HYDROXYPROGESTERONE
4	Urine Iodine

✓

✓