COMPLICATION OF QUESTIONS & ANSWERS RELATED TO IVD ISSUES

Issue Categories	Questions	Answers
Risk Classification of IVD Medical Devices		
Risk Classification	I would like to counter confirm that a **closed system analyzer** could be registered as Class A IVD medical device alone while the reagents could be registered separately based on their classification risk	1. A closed system analyzer could be registered as Class A IVD medical device alone Answer: YES 2. The reagents could be registered separately based on their classification risk Answer: YES Refer to possible way- analyzer
Risk Classification	Possible Ways to Register IVD Analyzer 1. How to register open-system analyzer (PCR machine) in Class A through route 1? 2. And do we still need to show proof of open-system of our analyzer in order to register in Class A?	1. Yes you may register as class A if the analyzer confirms fall through route 1, without reagents/kit/calibrator 2. You are not required to provide the proof for open-system analyzer as long as it confirms fall in class A and through route 1
Risk Classification	What is the correct risk- based classification for **Stick/Simple Rotavirus** and **Rotavirus/Adenovirus**?	JKTP Meeting Bil 16/2023 had decided to register this device as class B device as in other recognised countries, similar devices were registered with class B classification.
Risk Classification	What is the correct risk- based classification and classification rule of Pap smear Automation Preparation. Intended use of the devices: The Thinprep 5000 system is	The correct risk-based classification for this device is Class B, Rule 6

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	intended as a replacement for conventional method of pap smear preparation for use in screening for the presence of atypical cells, cervical cancer, or its precursor lesions (low grade squamous intraepithelial lesions, high grade squamous intraepithelial lesions), as well as all other cytologic categories as defined by the bethesda system for reporting cervical/vaginal cytologic diagnosis.	
Risk Classification	What is the correct risk- based classification for **Vibrio Antisera** Product?	JKTP Meeting Bil 15/2023 has decided Vibrio Antisera Product as class C device.
Risk Classification	What is the correct risk-based classification of Blood Gas Analyzer? Class B, Rule 6 or Class C, Rule 4?	It depends on the intended user of the blood gas analyser. According to the guidance document on classification of IVD device, Point-of-care testing (POCT) is defined as medical testing at or near the site of patient care by specially trained healthcare professionals. These are tests which can be performed at the bedside and typically involve blood and urine testing. The goal of POCT is to collect the specimen and obtain accurate results in a very short period of time at or near the location of the patient. POCT is often accomplished through the use of transportable, portable, and handheld instruments (e.g., blood glucose meter, INR meter). Bench analysers are also available for blood gas, pH, electrolyte, metabolite and haemoglobin measurement. Urinalysis analysers are also available for rapid and accurate urine testing. As per in guidance document, **point of care blood gas analyzers classified as class C, Rule 4**. But as from your information, the ABL8xx analyzers are intended for laboratory use only and not for near-patient use as per refer to ABL800

		FLEX Operator's Manual. The size of the analyzer mentioned also in not portable. It is recommended blood samples are analyzed as soon as possible, but within 30 min for samples collected with syringes, and within 10 min for samples collected with capillaries. This gives sufficient time for samples to be transported from the patient bed-site to a hospital laboratory to be immediately analysed. Considering these points, would it be more appropriate for the device to **fall under "Class B" Rule 6.**
Grouping of IVD Medical Devices		
Grouping for pregnancy test kit	Can we accept the pregnancy test kits with different number of packaging can be group as IVD Test Kit?	Cannot because the correct grouping is FAMILY grouping. The permissible variants are number of packaging.
Grouping for IVD Cluster	If we have the Indian Ink Reagent Dropper and PYR Reagent Dropper with the different in the cluster category can be group as SET grouping?	Cannot because the both reagents have different cluster category. India Ink Reagent Droppers- Fungal Infection PYR Reagent Droppers- Bacterial Infection The reagent needs to split according to the same methodology, cluster category and test principle.
Grouping for HIVST	What is the suitable grouping for HIV 1.2 Rapid Test Cassette for Self-Testing which have **multiple specimen** options which are whole blood, oral fluid and urine specimen.	Separate the application based on the different specimen options.

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Inquiry on HIV Self-Test Registration		
Inquiry on HIVST Evaluation:	Which laboratory are accepted by MDA that we can send to perform HIV Ag/Ab 2 in 1 Rapid Test Device (Self-Test).	As stated in the guidance document- PLACEMENT OF HIV SELF-TEST (HIVST) KIT IN MALAYSIA MARKET, the applicant needs to go to testing facility, i.e. Institute Medical Research (IMR) or any accredited local institute/laboratory with ISO 15189, Medical laboratories - Requirements for quality and competence.
Inquiry on HIVST Registration:	HIV SELF TEST (CE-marked) is registered with MDA. One company is interested to register a similar product variant which is non-CE with WHO PQ approved in Malaysia. Both CE-marked and WHO PQ approved products are identical as their manufacturing process, quality, safety and performance are exactly the same. May I seeking your advice whether can the WHO PQ approved products be added into current license via change notification submission.	It has been confirmed that change notification on the non-CE with WHO PQ approved is not allowed to be added with the current registered device. Therefore, it needs a new registration with full conformity assessment.
Inquiry on Covid-19 Registration		
Inquiry on Covid-19 Registration:	Are we allowed to add new sample type on Covid-19 test kit that has been registered via change notification? Previously, we registered for Covid-19 Test Kit (saliva only), but we are proposed to add new sample type for saliva + nasal	The change notification on the addition of samples to the approved test kit is not allowed. Therefore, it needs a new registration.

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<tr><td>Inquiry on Covid-19 Registration:</td><td>What is the sample size for Preclinical Studies Report for COVID-19 product</td><td>There is no specific sample size for Preclinical Studies Report as long as all the studies reports are comprehensive together with the raw data were submitted for COVID-19 test kit:
-Analytical sensitivity (LOD)
-Analytical specificity (Cross reactivity)
-Interference and other pre-clinical studies reports.</td></tr>
<tr><td colspan="3">Inquiry on Self-test Kit Registration</td></tr>
<tr><td>Self-test Kit registration:</td><td>Inquiry on Flu A/B + COVID 19 Test Kit (Self-Test) Registration:</td><td>Currently no policy set by KKM on self-test influenza. To launch the particular self-test for influenza in Malaysia might not be suitable unless the policy has been established.</td></tr>
<tr><td>Self-test Kit registration:</td><td>Inquiry on Troponin I Self-Test Kit Registration:</td><td>Currently no policy set by KKM on self-test Troponin I.</td></tr>
<tr><td>Self-test Kit registration:</td><td><table><tr><th>No.</th><th>Product</th><th>Specimen</th></tr><tr><td>1</td><td>Vaginal pH Rapid Test Panel</td><td>Vaginal secretion</td></tr><tr><td>2</td><td>H. Pylori Antigen Rapid Test Cassette</td><td>Feces</td></tr><tr><td>3</td><td>FOB Rapid Test Cassette</td><td>Feces</td></tr><tr><td>4</td><td>Ferritin Rapid Test Cassette</td><td>Whole Blood</td></tr><tr><td>5</td><td>SP-10 Male Fertility Rapid Test Cassette</td><td>Sperm</td></tr><tr><td>6</td><td>TSH Rapid Test Cassette</td><td>Whole Blood</td></tr><tr><td>7</td><td>Vitamin D Rapid Test Cassette</td><td>Whole Blood</td></tr><tr><td>8</td><td>Urinary Tract Infections Test Dipstick</td><td>Urine</td></tr></table>Inquiry on Self-test Kit registration:</td><td>We need a policy from KKM for an infectious disease self-test kit. However, for the non-infectious disease, MDA didn't have any restriction for registration.
For this query, H. Pylori Antigen Rapid Test Cassette and Urinary Tract Infections Test Dipstick are not allowed for self-testing as they are infectious disease test kits.</td></tr>
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CSDT & Essential Principles of Safety & Performance (EPSP)for In-Vitro Diagnostics Devices		
EPSP IVD	Class A need EPSP?	It is not compulsory for class A.
CSDT IVD: Specific part- Additional requirements for IVD medical device for self-testing and near patient testing	Please explain more on the Additional Requirements for IVD Medical Device for Self-Testing and Near Patient Testing.	Show the handling suitability of IVD MD and determine MD's performances when used by intended users following instructions provided in the labelling and without assistance from the professionals. Also, there shall be a study to show that the correct result can be obtained by the intended users, when compared to the laboratory professionals. Self-test results VS Professional Test. The reports shall conclude that the devices can be used accordingly by the target user.
CSDT IVD: List of record from recognised countries.	If there are 6 recognized countries records, do they need to list all in the respective section?	Yes, please list down all. This is for the record purposes.
Others		
Pre-market Approval	The product intends to register is classified as a Class C IVD medical device, and this product only has the EC Declaration of Conformity/Self-declared. This product doesn't have the CE Certificate and other premarket approval from reference countries. However, this product is listed in EUDAMED. Thus, the product listed in EUDAMED can go through the verification process by CAB. As referred to the Circular 2/2014, if the product is listed in EUDAMED, the product can go through a Verification process by CAB.	As referred to the Circular 2/2014, if the product is listed in EUDAMED, the product can go through a Verification process by CAB

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Clinical performance of the devices	Clinical performance requirements for HIV 4th generation test kit. What is the minimum sensitivity and specificity for detection of p24 antigen as well as the antibodies? Is there specific requirement for sample size for both antigen and antibody as well?	We didn't have any special/specific guideline for the HIV professional use test kit. But, testing conducted for Clinical Evidence should have adequate sample size according to prevalence of the disease.
Change Notification- Addition for IVD Cluster	Can we submit the change notification for addition of new type of drug abuse rapid test in the IVD Cluster?	Not allowed because the new type of drug abuse rapid test need go to conformity assessment for CAB.
Others	An IVD Test Kit will be used in a study intended for forensic use only and has no intention on medical purpose. Registration requirement on the medical device labelled as “IVD” but with intended for forensic use only?	Labels resumed are determined by manufacturer, not by the end user. If the manufacturer intends the device for in vitro diagnostic use only, however the user uses for a different purpose, the consequences will fall with the user. Manufacturer not liable for any incidents that happen due to wrong use or intend.
Others	Class D IVD test kit e.g. HbsAg test kit that has obtained CE certificate, certain manufacturers offer 2 options - with CE batch release or without CE batch release. Both with or without CE batch release has no difference in terms of production and identifier. The difference is that the manufacturer does not send the new batch of kits to EU Reference Laboratory for batch testing before placing in the market. Can we import and place the version without CE batch release?	As long as the identifier is registered with MDA, the importation and placement on the market are allowed.