



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	EZLAB HIV RAPID TEST DEVICE (ORAL FLUID) (FOR SELF-TESTING)
<b>ESTABLISHMENT NAME</b>	PREMIER DIAGNOSTICS SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	MANUFACTURER
<b>REGISTRATION NO</b>	IVDD8372424-192578
<b>BRAND NAME</b>	EZLAB
<b>MEDICAL DEVICE CATEGORY</b>	Immunology
<b>DEVICE GROUPING TYPE</b>	IVD TEST KIT
<b>DEVICE DESCRIPTION</b>	<p>The HIV Rapid Test Device (Oral Fluid) detects antibodies to HIV-1/HIV-2 through visual interpretation of color development on the internal strip. Recombinant HIV-1/2 antigens are immobilized on the test region of the membrane. The oral fluid specimen collector by the user, will be chased by buffer and then migrates along the internal strip by capillary action. And then interacts with sample pad, the target antibodies will bind to mouse anti-human IgG conjugated to colored particles and precoated onto the conjugate pad. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient HIV- 1/HIV-2 antibodies in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.</p>
<b>DEVICE INTENDED PURPOSE</b>	<p>The HIV Rapid Test Device (Oral Fluid) is a rapid visual immunoassay for the qualitative, presumptive detection of antibodies to HIV-1/HIV-2 in human oral fluid. This kit is intended for use as an aid in the diagnosis of HIV infection. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.</p>
<b>VALIDITY DATE OF REGISTRATION</b>	27/12/2024 - 26/12/2029

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	EZLAB HIV Rapid Test Device (Oral Fluid) (For Self-Testing)	EZ-HIV-S23
2	Individually packed swabs	EZ-HIV-S23
3	Extraction Buffer	EZ-HIV-S23
4	Waste bag	EZ-HIV-S23

NO	NAME OF DEVICE	IDENTIFIER
5	Package Insert	EZ-HIV-S23



**MEDICAL DEVICE AUTHORITY**