



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	TIGSUN 3-IN-ONE VAGINITIS ANTIGEN RAPID TEST
<b>ESTABLISHMENT NAME</b>	BLES MEDIC SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	IVDC5473823-125510
<b>BRAND NAME</b>	TIGSUN 3-IN-ONE VAGINITIS ANTIGEN RAPID TEST
<b>MEDICAL DEVICE CATEGORY</b>	Immunology
<b>DEVICE GROUPING TYPE</b>	IVD TEST KIT
<b>DEVICE DESCRIPTION</b>	The medical device is called TIGSUN 3-IN-ONE Vaginitis Antigen Rapid Test. This is a Latex Chromatography technology that allows the Clinicians to qualitatively detect organisms that are present in women's vaginal fluid namely <i>Candida albicans</i> , <i>Trichomonas vaginalis</i> and <i>Gardnerella vaginalis</i> .
<b>DEVICE INTENDED PURPOSE</b>	This kit is suitable for the in vitro qualitative detection of <i>Candida</i> , <i>Trichomonas vaginalis</i> , <i>Gardnerella vaginalis</i> antigens in female vaginal swab samples. This product is used as an aid in the diagnosis of <i>Candida</i> , <i>Trichomonas vaginalis</i> and <i>Gardnerella vaginalis</i> infections. <i>Candida</i> vaginitis is one of the most common female vaginitis caused by <i>Candida</i> infection. Candidiasis is the most common vaginal disease after bacterial vaginosis. Due to its difficult-to-treat and recurring nature, <i>Candida</i> vaginitis is more harmful to pregnant women, increasing complications such as premature rupture of membranes, contamination of amniotic fluid, preterm labor and infections during and after delivery, leading to premature birth, fetal infections and malformations, threatening the health of both mother and child. <i>Trichomonas vaginalis</i> is a common gynecological condition caused by <i>Trichomonas vaginalis</i> (TV) infection. <i>Trichomonas vaginalis</i> is a species of eukaryotic organism with flagella that lives in the human vagina and urinary tract. <i>Trichomonas vaginalis</i> infection is a widespread non-viral genital tract infection and is currently one of the most prevalent sexually transmitted diseases: it is associated with many perinatal complications, male and female genital tract infections and transmission and an increased incidence of HIV. Bacterial vaginosis (BV) is a common clinical syndrome in women of childbearing age, characterized by a shift in the microflora of the reproductive tract, as the overwhelmingly dominant lactobacilli are replaced by high concentrations of <i>Gardnerella vaginalis</i> (GV) and a range of potentially pathogenic microorganisms associated with bacterial vaginosis. <i>Gardnerella vaginalis</i> (GV) and a range of potentially pathogenic microorganisms associated with bacterial vaginosis. <i>Gardnerella vaginalis</i> is a common cause of bacterial vaginosis and is responsible for urethritis, endometritis, and atypical cervical epithelial hyperplasia. Pregnant women with <i>Gardnerella vaginalis</i> infection can have preterm labor, premature rupture of membranes, chorioamnionitis, puerperal infections, low birth weight newborns and increased susceptibility to HIV. Mixed vaginitis is an inflammation of the vagina caused by two or more pathogenic organisms. Mixed vaginitis is more difficult to treat than single vaginal infections. The most common types of mixed vaginitis are <i>Candida</i> vaginitis (VVC) combined with bacterial vaginosis (BV) infection and <i>Trichomonas</i> vaginitis combined with bacterial vaginosis (BV) infection. The clinical presentation of mixed vaginitis is varied and atypical.

**VALIDITY DATE OF  
REGISTRATION**

23/03/2023 - 22/03/2028

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Tigsun VVC/TV/GV Combo Antigen Test 25 x Individual sealed pouches; each contains 1 test cassette	2001S
2	1 bottle sample dilutions(or 25 x Reagent Tube prefilled with sample dilution)	(not set)
3	25 x Reagent Tube	(not set)
4	25x Swabs	(not set)
5	1 x Instructions for use	(not set)



**MEDICAL DEVICE AUTHORITY**