



DEVICE DETAILS

NAME OF DEVICE	TIGSUN GBS ANTIGEN RAPID TEST
ESTABLISHMENT NAME	BLES MEDIC SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	IVDC9200323-125510
BRAND NAME	TIGSUN GBS ANTIGEN RAPID TEST
MEDICAL DEVICE CATEGORY	Immunology
DEVICE GROUPING TYPE	IVD TEST KIT
DEVICE DESCRIPTION	<p>This kit is suitable for the in vitro qualitative detection of group B streptococcal antigens in swab samples of female genital tract secretions. Group B streptococcus (GBS) is a Gram-positive streptococcal bacterium that is normally found in pairs or in short chains in the vagina and rectum. It is a conditionally pathogenic bacterium that can cause neonatal sepsis, pneumonia, meningitis, and even death. Newborns who survive the infection may also have severe neurological sequelae, including hydrocephalus, mental retardation, microcephaly, and deafness. At the same time, group B streptococcus can also cause infection in pregnant women, causing preterm delivery, fetal hypoplasia (low birth weight babies), premature rupture of membranes and late miscarriage. The health of pregnant women and newborns is seriously endangered. It has attracted the attention of clinicians worldwide. In the laboratory diagnosis of group B streptococcal infections, the method of culture isolation of the pathogen is specific but time-consuming, which is not conducive to timely diagnosis and treatment. This product is a rapid immunological method that can detect live or dead organisms directly from vaginal and cervical secretions, providing a basis for clinical diagnosis of group B streptococcal infections. For in vitro diagnostic use only. For professional use only.</p>
DEVICE INTENDED PURPOSE	<p>This kit is suitable for the in vitro qualitative detection of group B streptococcal antigens in swab samples of female genital tract secretions. Group B streptococcus (GBS) is a Gram-positive streptococcal bacterium that is normally found in pairs or in short chains in the vagina and rectum. It is a conditionally pathogenic bacterium that can cause neonatal sepsis, pneumonia, meningitis, and even death. Newborns who survive the infection may also have severe neurological sequelae, including hydrocephalus, mental retardation, microcephaly, and deafness. At the same time, group B streptococcus can also cause infection in pregnant women, causing preterm delivery, fetal hypoplasia (low birth weight babies), premature rupture of membranes and late miscarriage. The health of pregnant women and newborns is seriously endangered. It has attracted the attention of clinicians worldwide. In the laboratory diagnosis of group B streptococcal infections, the method of culture isolation of the pathogen is specific but time-consuming, which is not conducive to timely diagnosis and treatment. This product is a rapid immunological method that can detect live or dead organisms directly from vaginal and cervical secretions, providing a basis for clinical diagnosis of group B streptococcal infections. For in vitro diagnostic use only. For professional use only.</p>
VALIDITY DATE OF REGISTRATION	23/03/2023 - 22/03/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Tigsun GBS Antigen Rapid Test	Tg- 2008
2	25x Individual sealed sachets	Same as above
3	1 bottle treatment reagent A	Same as above
4	1 bottle treatment reagent B	Same as above
5	25 x reagent tubes and caps	Same as above
6	25x cotton swab	Same as above
7	1X Instruction	Same as above



MEDICAL DEVICE AUTHORITY