

UPUTSTVO ZA UPOTREBU (SRB)

Chromogenic Strep B Selective Agar Plate

Podloga je preporučena za selektivnu izolaciju Streptokoka grupe B.

Sadržaj pakovanja:

Šifra artikla (pakovanja) REF	Opis	Šifra primarnog pakovanja:	Broj podloga
PRM1840V20	Podloga izlivena u petri posudama od ø90	PRM1840	20
PRM1840V60			60
PRM1840V240			240
PRM1840M40	Podloga izlivena u petri posudama od ø50		40

Uputstva

Pod aseptičnim uslovima inokulisati ploču metodom površinskog zasejavanja. Nakon inkubacije posmatrati rast i boju kolonija.

Princip i interpretacija

Grupa B streptokoka (GBS) je glavni uzročnik infekcija koje izazivaju bolesti i smrt kod novorođenčadi. Streptococcus spp. grupe B takođe može biti uročnih ozbiljnih bolesti kod trudnica, starijih i osoba obolelih od drugih bolesti. GBS se normalno nalaze u vaginalnoj flori kod žena i u rektumu kod muškaraca i žena (1). Kod novorođenčadi, Streptokoke grupe B su najčešći uzročnik sepse (infekcije krvotoka) i meningitisa (infekcija moždanih ovojnica i likvora) i čest uzročnik pneumonije. Kod odraslih GBS retko može dovesti do ozbiljnih infekcija krvotoka, infekcija urinarnog trakta, kožnih infekcija i pneumonije, posebno kod ljudi sa slabim imunološkim sistemom. Prisustvo velikog broja kolonija u genitalnom traktu trudnica povezano je sa infekcijom novorođenčadi i rizikom od neonatalnih oboljenja (2).

Prikupljanje uzoraka se obično vrši uzimanjem vaginalnog i rektalnog brisa između 35. i 37. nedelje trudnoće. Uzorak se zatim obrađuje na podlozi Chromogenic Strep B Selective Agar Plate. Za konveksionalne metode optimalan oporavak ćelija se ipak postiže selektivnim obogaćenjem u Todd Hewitt bujonu sa kolistinom i nalidiksinskom kiselinom, a potom subkultivacijom na krvnom agaru (3,4).

Hidrolizat proteina obezbeđuje esencijalne hranjive materije za razvoj streptokoka. Sadržaj pufera obezbeđuje puferovanje podloge. Selektivni agensi u podlozi inhibiraju prateću mikrobiotu. Jedan od supstrata u hromogenoj mešavini se razgrađuje od strane beta-glukozidaze koju sintetisuje Streptokoke grupe B, što rezultira bojenjem kolonija u plavo.

Kontrola kvaliteta

Podaci i rezultati kontrole kvaliteta dati su u sertifikatu analize za svaku seriju.

Skladištenje i rok upotrebe

Čuvati između 2-8°C. Upotrebiti pre isteka datuma označenog na nalepnici.

Mere predostrožnosti



Ovaj proizvod ne sadrži hazardne supstance u koncentracijama koje su iznad propisanih limita određenih važećim zakonskim regulativama i zato nije klasifikovan kao opasan. Ipak, preporučeno je slediti smernice iz bezbednosnog lista za pravilnu upotrebu. Ovaj proizvod je namenjen isključivo za upotrebu u laboratorijskim uslovima, od strane profesionalno obučene osobe.


Proizvod ne upotrebljavati ukoliko je primarno pakovanje oštećeno ili proizvod ne odgovara navedenim karakteristikama.

Odlaganje otpada

Odlaganje otpada mora biti u skladu sa nacionalnim i lokalnim regulativama koje su na snazi. Svaka laboratorija je odgovorna za rukovanje i odlaganje otpada koji nastaje u toku rada.

Upotrebljeni simboli

	Evropski znak usaglašenosti		Držati uspravno
	In vitro dijagnostičko medicinsko sredstvo		Kataloški broj
	Ne izlagati direktno sunčevim zracima		Lot broj
	Konsultovati uputstvo za upotrebu		Rok upotebe
	Ne koristiti više puta		Temperatura čuvanja
	Veličina pakovanja		Proizvođač
	Ovlašćeni predstavnik u Evropskoj uniji		

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Literatura

- Anthony BF, Okada DM, Hobel CJ. Epidemiology of group B Streptococcus: longitudinal observations during pregnancy. J Infect Dis 1978; 137:524-30.
- Murray P.R., Baron J.H., Tenover FC, Tenover FC, (Eds.), 2003, Manual of Clinical Microbiology, 8th Ed., American Society for Microbiology, Washington, D.C.
- Prevention of perinatal group B Streptococcal disease: a public health perspective. Centres for Disease control and Prevention. MMWR Recomm Rep 1996; 51:1-22
- NHS Processing swabs for Group B Streptococcal carriage Issue no.2.1,2006

Broj rešenja o registraciji: 515-02-02534-22-003

INSTRUCTION FOR USE (EN)

Chromogenic Strep B Selective Agar Plate

Medium is recommended for selective isolation of Group B streptococci

Package contents:

Item code (packaging) REF	Description	Primary packaging code:	Number of products
PRM1840V20	Substrate poured into petri dishes of ø90	PRM1840	20
PRM1840V60			60
PRM1840V240			240
PRM1840M40	Substrate poured into petri dishes of ø50		40

Directions

Surface spread the test inoculum aseptically on the plate. After incubation, observe growth and color of colonies.

Principle and interpretation

Group B *Streptococcus* is a leading infection causing illness and death in newborns. Group B streptococci can also cause serious diseases in pregnant women, the elderly, and adults with other illnesses. GBS normally reside in the vagina of women and rectum of men and women (1). In newborns, group B strep is the most common cause of sepsis (infection of the bloodstream) and meningitis (infection of the lining and fluid surrounding the brain) and a common cause of pneumonia.

In adults, group B strep can rarely lead to serious bloodstream infections, urinary tract infections, skin infections, and pneumonia, especially in people with weak immune systems. Heavy colonization of the maternal genital tract is associated with colonization of infants and risk of neonatal disease (2).

The sample collection is usually done by collection of vaginal and rectal swab between 35 and 37 weeks of pregnancy. The swab is then processed on Chromogenic Strep B Selective Agar Plate. For the conventional methods optimum recovery is however achieved by selective enrichment into Todd Hewitt broth with colistin and nalidixic acid and then subculture on Blood Agar (3,4).

Protein hydrolysate provides essential nutrients for the growth of Streptococci. Buffers present provides buffering to the medium. Selective agents in the medium inhibits accompanying flora. One of the substrate in the chromogenic mixture is cleaved by beta glucosidase possessed by Group B Streptococci resulting in blue coloured colonies.

Quality control

The data and results of quality control are given in the certificate of analysis for each lot.

Storage and shelf life

Storage between 2-8°C. Use before expiry date on the label.














Warning and precautions


In vitro diagnostic use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques.

Symbols used on labels

	European Conformity mark		This side up
	is an in vitro diagnostic medical device (IVD)		Catalogue number
	Do not expose directly to sunlight		Batch code
	Consult instructions for use		Use-by date
	Do not re-use		Temperature limit
	Pack size		Manufacturer
	European Authorized Representative (Authorised Representative)		

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Reference

1. Anthony BF, Okada DM, Hobel CJ. Epidemiology of group B Streptococcus: longitudinal observations during pregnancy. J Infect Dis 1978; 137:524-30.
2. Murray P.R., Baron J.H., Manual of Clinical Microbiology Murray P. R., Baron J. H., Tenover F.C., Tenover F.C., (Eds.), 2003, Manual of Clinical Microbiology, 8th Ed., American Society for Microbiology, Washington, D.C.
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