BIO-RAD

PASTOREX™ MENINGITIS

25 tests

61607	61611	61616
61608	61613	61618
61610	61614	61717

DETECTION OF SOLUBLE ANTIGENS AND IDENTIFICATION OF *NEISSERIA MENINGITIDIS* A, C, Y/W135, B/*E.COLI* K1, *HAEMOPHILUS INFLUENZAE* b, *STREPTOCOCCUS PNEUMONIAE, STREPTOCOCCUS* B

IVD

1- CLINICAL VALUE

Bacterial meningitis is an infection of the meninges and the main causative organisms are: *Neisseria meningitidis, Streptococcus pneumoniae, Haemophilus influenzae* type b, and *Streptococcus* group B.

Meningitis is a serious situation, so it is important to diagnose the infection rapidly in order to start appropriate treatment. The conventional technique of identification by culture, even though essential for the antibiogram and confirmation of the diagnosis, is slow and can give false negative results if the specimen has been transported and stored under unsatisfactory conditions, or if an antibiotic therapy has been initiated before the specimen was taken.

Immunological techniques for detecting soluble antigens released by the causative organisms into biological fluids e.g. cerebrospinal fluid, urine, serum, during the infection, permit a more rapid diagnosis. The soluble antigens that can be detected with this kit are the polysaccharides specific for certain serogroups or serotypes : *Streptococcus pneumoniae* (83 types); *Haemophilus influenzae* type b, *Neisseria meningitidis* group A, group B/*E.coli* K1, group C, group Y/W135, and *Streptococcus* group B.

The polysaccharide antigen specific for Meningococcus serogroup B is only very slightly antigenic and it has always been very difficult to obtain reproducible rabbit antibodies specifically directed against this antigen. Monoclonal antibody technology applied to the preparation of specific bacterial polysaccharide antigens allows the production of monoclonal mouse antibodies capable of specifically and reproducibly recognising the polysaccharide antigen of Meningococcus serogroup B.

This polysaccharide antigen specific for Meningococcus serogroup B, is identical to a polysaccharide antigen found with *E.coli* K1. This antigenic homology between Meningococcus B and *E.coli* K1 permits the diagnosis of *E.coli* meningitis in newborns, of which about 80 % are of the K1 strain.

It should be noted that *E.coli* and *Streptococcus* B are the principal bacteria responsible for meningitis in the newborn and premature infants, and that the meningococcal infection is extremely rare in this age group.

2- PRINCIPLE

Antigen contained in the specimen tested is identified using latex particles coated with specific homologous antibodies. In the presence of the homologous antigen, latex particles agglutinate. In the absence of antigen, they remain in a homogenous suspension.

3- PRESENTATION

1. PASTOREX™ MENINGITIS 25 test kit, code 61607, consisting of :

- Reagent 1 (R1): *N. meningitidis* B/*E.coli* K1
  1 bottle with 0,40 ml of red latex sensitized with mouse monoclonal antibody specific for *N. meningitidis* group B/E.coli K1.
- Reagent 2 (R2): *N. meningitidis* B/*E.coli* K1 negative control
  1 bottle with 0,40 ml of red latex sensitized with mouse monoclonal antibody specific for tetanus toxoid.
- Reagent 3 (R3): *H. influenzae* b
  1 bottle with 0.40 ml of white latex sensitized with rabbit antibodies specific for *H. influenzae* type b.
- Reagent 4 (R4): *S. pneumoniae*
  1 bottle with 0.40 ml of green latex sensitized with rabbit antibodies specific for *S. pneumoniae*.
- Reagent 5 (R5): *Streptococcus* B
  1 bottle with 0.40 ml of yellow latex sensitized with rabbit antibodies specific for *Streptococcus* B.
- Reagent 6 (R6): *N. meningitidis* A
  1 bottle with 0.40 ml of blue latex sensitized with rabbit antibodies specific for *N. meningitidis* group A.
- Reagent 7 (R7): *N. meningitidis* C
  1 bottle with 0.40 ml of red latex sensitized with rabbit antibodies specific for *N. meningitidis* group C.
- Reagent 8 (R8): *N. meningitidis* Y/W 135
  1 bottle with 0.40 ml of pink latex sensitized with rabbit antibodies specific for *N. meningitidis* Y/W 135
- Reagent 9 (R9): Control polyvalent negative
  1 bottle with 0.40 ml of plum latex sensitized with IgG immunoglobulins from non immunized rabbit.
- Reagent 10 (R10): Control polyvalent positive
  Positive control: freeze dried antigenic extract to be reconstituted with 1 ml sterile water. Contains the polysaccharide antigens of *N. meningitidis* A, C, B, Y/W135, *H. influenzae* b, *Streptococcus* B, and *S. pneumoniae*. Volume sufficient for 20 reactions.
  All the reagents contain 0.02 % thimerosal.

Reagents R1, R2, R3, R4, R5, R6, R7, R8, R9 contain less than 0.1% sodium azide.

- Disposable agglutination cards.
- Disposable mixing sticks.

2. PASTOREX™ MENINGITIS INDIVIDUAL LATEX TESTS (25 tests each):

- Single latex test (without control)
  - *N. meningitidis* A (R6) code 61608
  - *N. meningitidis* C (R7) code 61610
  - *N. meningitidis* B / *E. coli* K1 (R1) code 61611
  - *Streptococcus* B (R5) code 61613
  - *Streptococcus pneumoniae* (R4) code 61614
  - *Haemophilus influenzae* b (R3) code 61616
- PASTOREX™ MENINGITIS control

  Control reagents kit for single latex test (for 2 x 25 tests) code 61618
  - 2 dropper bottles with 0.40 ml of polyvalent negative control (R9)
  - 2 bottles of freeze dried polyvalent positive control (R10) to be reconstituted with 1 ml of sterile water
  - 2 dropper bottles with 0.40 ml of negative control for N.m.B / *E.coli* K1 (R2)
  - disposable cards.
  - disposable mixing sticks.

3. PASTOREX™ MENINGITIS Diluent

1 bottle with 40 ml of diluent for sera treatment code 61717

4- STORAGE

All reagents are stable until the expiry dates indicated on the label, if stored at +2-8°C and in absence of microbial contamination (even once open).

The reconstituted polyvalent positive control R10 is stable for 1 month at +2-8°C (in absence of microbial contamination) or longer if aliquoted and frozen at -20°C immediately.

Store the latex reagent bottles upright.

THE LATEX REAGENTS MUST NOT BE FROZEN.

5- NECESSARY MATERIAL NOT SUPPLIED

- Pipette for distributing one drop (40 to 50µl) of the specimen.
- Haemolysis or Eppendorf tubes
- Dry incubator or water-bath at 100°C.
- Centrifuge for haemolysis or Eppendorf tubes.
- Disinfectant bath
- Sterile distilled water, sterile saline or diluent (code 61717)

6- PRECAUTIONS

The quality of results depends on complying strictly with Good Laboratory Practice.

- All the reagents and the sample should be used at a room temperature between 18 and 25°C.
- Do not touch the reaction surface of the agglutination cards.
- Change the pipette or disposable tip for each sample tested.
- Shake the bottles of latex before use.
- Wipe the tip of the reagent dropper bottle in order to obtain well calibrated drops.
- Hold the reagent bottle vertical to deposit drops.
- Change the mixing stick for each reaction.
- Discard all disposable material used in an autoclavable waste bin or disinfectant bath.
- The polyvalent positive control should be reconstituted with distilled sterile water avoiding any contamination.

HYGIENE AND SAFETY INSTRUCTIONS

Always observe the current techniques and precautions concerning protection against microbiological hazards.

- All samples taken must be considered potentially infectious.

7- PROCEDURE: CSF, serum, urine

Samples

Samples should be treated as soon as possible after collection. If this is not possible, they can be stored for a few hours between +2 and +8°C, or longer at -20°C (In this case, keep only the supernatant at –20°C after centrifugation). Avoid repeated freezing / thawing. Bacteriological examinations (culture) should be performed as a matter of priority in order to avoid contamination of the sample. The minimum volume of sample for testing with the latex kit is 0.5 ml.

A) PREPARATION OF CLINICAL SAMPLES

CAUTION: when using a water-bath, use watertight tubes to keep water from entering the tubes. Use a dry incubator if possible.

a) CSF (cerebrospinal fluid)

If the CSF is very turbid or contains red blood cells, centrifuge it for 5 minutes at 350 g and collect the supernatant.

- Heat the sample for 3 minutes at 100°C (dry incubator or water-bath). Allow the sample to cool to room temperature, then perform centrifugation for 5 minutes at 3000 g or filtration using a filter with 0.45 µm filter.

b) Serum

- Add 3 volumes (1,5 ml) of diluent (code 61717) for one volume (0,5 ml) of serum.
- Heat for 3 minutes at 100°C in a water-bath or dry incubator.
- Centrifuge for 5 minutes at 3000 g.

CAUTION: Do not use plasma samples. Interference due to an overload of albumin, lipid, haemoglobin and bilirubin have not been tested. Best results are obtained using fresh serum.

c) Urine

To increase the antigen concentration, prior to testing, the sample can be concentrated up to 25 fold on an Amicon B15-type membrane (www.millipore.com/amicon).

- Heat the urine for 3 minutes at 100°C (dry incubator or water-bath).
- Centrifuge for 5 minutes at 3000 g or filter using a 0.45µm filter.

B) TEST PROCEDURE.

- Place a drop (40 to 50 µl) of the pre-treated sample supernatant in each circle of the agglutination card
- Gently shake the latex reagent bottles.
- Holding the bottle upright, place one drop of each latex reagent on the disposable card following the indicated distribution pattern: R9, R6, R7, R1 and R2 in the white circles and R8, R3, R4 and R5 in the black circles.
- Mix the latex reagents and the sample using a rod; change the rod for each latex.
- Rotate the card (~120 RPM) gently for **10 minutes** and watch for the appearance of any agglutination visible to the naked eye within **10 minutes** (orbital type agitator can be used at a speed ~120RPM).

8- PROCEDURE: BLOOD CULTURE

For presumptive orientation check the morphology and the Gram stain

- Take 1 to 2 ml of a positive blood culture.
- Centrifuge for 5 minutes at 2000g
- Place one drop (40 to 50 µl) of supernatant in each circle on the disposable card, corresponding to the latex reagents to be tested, according to the Gram stain.
- Gently shake the latex reagent bottles selected for the test.
- Holding the bottle upright, place one drop of each selected latex reagent at the periphery of the supernatant drops.
- Mix the latex reagents and the sample using a rod, changing the rod for each latex.
- Rotate the card at ~120 rpm for **5 minute**. During this **5 minute** period, check for the appearance of agglutination.

Some blood culture media can result in non specific reactions or interpretation problems. As a negative control, use a blood culture inoculated with sterile blood or with a different organism other than those detected by PASTOREX™ Meningitis.

9- INTERPRETATION OF RESULTS

POSITIVE REACTION

A positive reaction is indicated by fine agglutination, visible to the naked eye, compared to the negative controls.

Agglutination intensity and time of appearance depends upon the concentration of antigen in the sample tested.

A discordance between a positive antigen test and a negative culture can be explained by the absence of viable bacteria in the cultured sample (antibiotic treatment started before the sample was taken or transport conditions not suited to the survival of fragile bacteria).

In most cases, a positive reaction with anti-*N. meningitidis B/E.coli* K1 latex in a new-born or premature infant indicates infection by *E.coli* K1. In an older subject, Meningococcus B is more probable. Culture of the sample must confirm the diagnosis.

NEGATIVE REACTION

Homogenous suspension, without clumps.

NON-INTERPRETABLE RESULTS

A reaction is un-interpretable if the sample agglutinates with the latex negative controls (R2 or R9) and/or with more than one latex reagent in the kit. In this case, it is advisable to repeat the test with another sample and wait for result of the culture. (Very rarely, an infection can be due to two different bacterial species).

10- **PROCEDURE:** GROUPING OF BACTERIAL STRAINS ISOLATED ON AGAR (Colonies from a fresh and pure culture)

Latex Y/W135 cannot be used for this grouping of bacterial strains. To determine these groups, it is recommended to use conventional antisera (Kit Y, W135, 29E: Ref # 58704, 3x1mL).

For a presumptive orientation prior to perform the test:

- Check the morphology and the Gram stain .
- For Gram-negative bacteria, test for oxydase (Positive for *N. meningitidis*, negative for *E.coli* K1).
- For Gram positive cocci perform a catalase test. (Do not test catalase positive strains).

Non-encapsulated *S.pneumonia* and *Haemophilus influenzae* strains cannot be identified by this technique.

a) Grouping: *N. meningitidis* (A, B, C only), *H. influenzae, E. coli, S. pneumoniae*

- Place a 30 µl drop of sterile saline solution in a circle on the disposable card.
- Sample:
  - For *Neisseria meningitidis, Haemophilus influenzea* and *Escherichia coli*, the equivalent of 1 µl loop, which is a **maximum** of 2 to 3 colonies.
  - For *Streptococcus pneumoniae*, the equivalent of 5 µl loop, which is a **minimum** of 10 to 12 colonies.
- Carefully emulsify the sampled colonies in such a way as to obtain a homogeneous suspension.
- Gently shake the latex reagent bottle chosen for identification; holding the bottle upright, place one drop of this latex at the periphery of the drop of bacterial suspension.
- Mix the latex and the suspension using a rod.
- Rotate the card (~120 rpm).
- Observe the appearance of any clear agglutination in less than **2 minutes**,
- Confirm the identification of the species using conventional biochemical testing.

b) Grouping: Steptococcus B (ß-haemolytic colonies)

- Suspend 5 colonies in 2 ml of Todd Hewitt broth.
- Incubate in 37°C water-bath for 2 to 3 hours.
- Centrifuge 5 minutes at 3,000 g.
- Place one drop (40 to 50 µl) of supernatant in a circle on the disposable card.
- Gently shake the latex reagent bottle; holding the bottle upright, place one drop of this latex at the periphery of the drop of supernatant.
- Mix the latex and the sample using a rod.

- Rotate the card (~120 rpm).
- Observe the appearance of any clear agglutination within less than **1 minute**.
- Confirm identification of the species using conventional biochemical tests.

For a direct extraction from isolated colonies, use PASTOREX™ STREP kit (Code 61721)

11- QUALITY CONTROL OF THE TEST

The latex reagents should be completely homogenous after shaking.

The positive polyvalent control R10 is used to verify each latex's immuno-reactivity.

- To perform this quality-control test, place one drop (40 µl) of the positive control (R10) in each circle on the disposable card.
- Gently shake the latex reagent bottles.
- Holding the bottle upright, place one drop of each latex reagent on the disposable card following the indicated distribution pattern: R9, R6, R7, R1 and R2 in the white circles and R8, R3, R4 and R5 in the black circles.
- Mix the latex reagents and the positive control using a rod, changing the rod for each latex.
- Rotate the card at ~120 rpm for **10 minute**. During this **10 minute** period, check for the appearance of any agglutination using the naked eye (compare the test latex reactions with those of the latex negative controls).

Agglutination intensity and rate of appearance depend on antigen/antibody avidity. As a result, the reactions observed with each latex are variable. Those of latex NmB/Coli K1 are finer than those of the others.

- A saline solution or the diluent (code 61717) controls the absence of unspecific agglutination of each latex.

  To perform this quality-control test, physiological saline or diluent R11 (code 61717) are used according to the protocol for the polyvalent positive control (cf. previous procedure).
- The latex reagents should not be used when, they do not agglutinate with polyvalent positive control (R10), or when they non-specifically agglutinate with saline or diluent (code 61717) (this could be due to incorrect storage conditions of the kit or a latex reagent contamination)

12- QUALITY CONTROL OF THE MANUFACTURER

All manufactured reagents are prepared according to our Quality System, starting from reception of raw material to the final commercialization of the product.

Each lot is submitted to quality control assessments and is only released to the market, after conforming to pre-defined acceptance criteria.

The records relating to production and control of each single lot are kept within Bio-Rad.

13- TEST PERFORMANCE

SENSITIVITY

The sensitivity of each reagent of the kit was determined by analysis of :

- purified antigens diluted in saline
- clinical samples of cerebrospinal fluid documented by the conventional techniques of analysis (culture, microscopic examination)
- strains isolated from culture on Mueller Hinton agar, chocolate + PVS agar, Columbia + 5% sheep blood agar.

Antigen or bacteria revealed in the sample	**Diluted antigen (NaCl, 9 ‰)**	**CSF**		**Strains**	
	limit concentration detected	number of samples analysed	number of positive latex test	number of samples analysed	number of positive latex test
N. meningitidis A	2,5 ng/mL	12	12	22	22
N. meningitidis B	62,5 ng/mL	ND		9	9
E. coli K1				1	1
N. meningitidis C	2,5 ng/mL	3	3	16	16
N. meningitidis Y	5 ng/mL	ND		-	-
N. meningitidis W	2,5 µg/mL	ND		-	-
S. pneumoniae	95 ng/mL	24	22	15	15
Streptococcus B	20 ng/mL	1	1	15	15
H. influenzae type b	0,1 ng/mL	34	33	17	17

SPECIFICITY

The specificity of each reagent was determined by analysis of:

- Sterile CSF (a) or CSF contaminated by bacteria responsible for meningitis and different from those detected by the latex test (b)
- Strains belonging to *genuses Neisseria, Branhamella, Acinetobacter, Streptococcus, Klebsiella, Haemophilus, Escherichia coli* non K1, *Pseudomonas* tested with heterologous latex.

Latex test	Sterile CSF (a)		Contaminated CSF (b)		Strains (c)	
	number of samples analysed	number of negative latex test	number of samples analysed	number of negative latex test	number of samples analysed	number of negative latex test
N. meningitidis A	52	52	50	50	122	122
N. m. B / *E. coli* K1	12	12	ND		53	48*
N. meningitidis C	52	52	56	56	127	127
S. pneumoniae	60	60	39	39	33	33
Streptococcus B	49	49	58	58	17	17
H. influenzae type b	61	61	32	32	31	31
	Unselected CSF					
	number of samples analysed		number of negative latex test			
N. meningitidis Y/W 135	40		40		-	-

*1/1 strain of *Neisseria flavescens*, 2/4 strains of *Klebsiella pneumoniae*, 2/5 strains of *Acinetobacter* gave non-specific reactions.

BLOOD CULTURES

Performances of PASTOREX™ MENINGITIS have been tested on blood cultures. The results of this evaluation are:

- Sensitivity: 100 % (4/4 including 2 strains of *S. pneumoniae* and 2 strains of *Streptococcus* B).
- Specificity: 100 % (37/37). For reagent R3, R4, R5, R6, R7 and R8.
- Specificity: 97,5% (39/40). For reagent R1.

Among the 3 blood cultures with *Klebsiella pneumoniae*, 1 gave a non-specific reaction.

14- LIMITS OF THE TECHNIQUE

- In numerous cases, immunologic latex technique allows a presumptive diagnosis of the organism. However, the antigen concentration in the sample may be below the lower limit of detection of the latex and produce a negative result. It can be useful in this case to repeat the sample at a later time.
- This technique cannot replace cultivation of the bacteria, which alone permits the establishment of an antimicrobial susceptibility result.
- Considering the wide variety of blood culture media, performances cannot be guaranteed for all media. (Cf. 7-D).
- Clinical and bibliographic data concerning the detection of antigens in sera and urine using latex reagents are limited at the present time.
- A few examples of unrelated bacteria possessing similar antigens have been reported. The possibility of cross-reactions should always be considered(1, 4, 5).
- The final diagnosis, as for all laboratory diagnoses, can not be based on the results of one single test, but on an overview of the clinical data and the biochemical, cytological and immunological results.
- Soluble antigen detection in blood culture as well as grouping of strains isolated on agar, should be completed by a species identification of the bacterial strain

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CE

(US) - CE marking (European directive 98/79/CE on *in vitro* diagnostic medical devices)
(F) - Marquage CE (Directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro*)
(E) - Marcado CE (Directiva europea 98/79/CE sobre productos sanitarios para diagnóstico *in vitro*)
(I) - Marchiatura CE (Direttiva europea 98/79/CE relativa ai dispositivi medico-diagnostici *in vitro*)
(D) - CE Konformitätskennzeichnung (Europäische Richtlinie 98/79/EG über *In-vitro*-Diagnostika)
(P) - Marcação CE (Directiva europeia 98/79/CE relativa aos dispositivos médicos de diagnóstico *in vitro*)
(S) - CE-märkning (Europeiskt direktiv 98/79/EG om medicintekniska produkter för *in vitro*-diagnostik)
(DK) - CE-mærkningen (Europa direktiv 98/79/EF om medicinsk udstyr til *in vitro*-diagnostik)
(GR) - Χαρακτηρισμος CE (ευρωπαικη οδηγια 98/79/CE περι *in vitro* διαγνωστικες ιατρικες συσκευες)
(PL) - CE oznaczenie (Dyrektywa unijna 98/79/CE dotyczaca produktów medycznych do badań *in vitro*)
(LT) - CE ženklas (Europos sąjungos direktyva 98/79/CE dėl *in vitro* diagnostikos medicinos prietaisų)
(H) - CE jelzés (98/79/CE Európai irányelv az *in vitro* orvosi diagnosztikai eszközökről)
(EST) - CE märgistus (Euroopa direktiiv 98/79/CE *in vitro* diagnostikameditsiiniseadmete kohta)
(SK) - CE označenie o zhode (Európska direktíva 98/79/CE pre *in vitro* diagnostické zdravotnícke postupy)
(CZ) - CE značka (Evropská direktiva 98/79/CE o diagnostických zdravotnických prostředcích *in vitro*)
(N) - CE-merking (EU-direktiv 98/79/CE om medisinsk utstyr til in vitro-diagnostikk)
(RO) - Marca CE (Directiva europeana 98/79/CE pentru dispozitive medicale de diagnostic *in vitro*)
(BG) - CE маркировка (Европейска директива 98/79/CE за ин витро диагностичните медицински изделия)

IVD

(US) - For *in vitro* diagnostic use
(F) - Pour diagnostic *in vitro*
(E) - Para diagnóstico *in vitro*
(I) - Per uso diagnostico *in vitro*
(D) - In-vitro-Diagnostikum
(P) - Para uso em diagnóstico *in vitro*
(S) - *In vitro*-diagnostik
(DK) - *In vitro* diagnose
(GR) - Για *in vitro* διαγνωστικη χρηση
(PL) - Do stosowania *in vitro*
(LT) - *in vitro* diagnostikai
(H) - Csak *in vitro* diagnosztikai alkalmazásra
(EST) - *In vitro* diagnostiliseks kasutamiseks
(SK) - Na diagnostiku *in vitro*
(CZ) - Pro diagnostiku *in vitro*
(N) - Til in vitro-diagnostikk
(RO) - Pentru diagnostic *in vitro*
(BG) - За ин витро диагностика

REF

(US) - Catalogue number
(F) - Référence catalogue
(E) - Número de catálogo
(I) - Numero di catalogo
(D) - Bestellnummer
(P) - Número de catálogo
(S) - Katalognummer
(DK) - Katalognummer
(GR) - Αριθμος καταλογου
(PL) - Numer katalogu
(LT) - Katalogo numeris
(H) - Cikkszám
(EST) - Katalooginumber
(SK) - Katalógové číslo
(CZ) - Katalogové číslo
(N) - Katalognummer
(RO) - Număr de catalog
(BG) - Каталожен номер

(US) - Manufacturer
(F) - Fabricant
(E) - Fabricante
(I) - Produttore
(D) - Hersteller
(P) - Fabricante
(S) - Tillverkad av
(DK) - Fremstillet af
(GR) - Κατασκευαστης
(PL) - Producent
(LT) - Gamintojas
(H) - Gyártó
(EST) - Tootja
(SK) - Výrobca
(CZ) - Výrobce
(N) - Produsent
(RO) - Producător
(BG) - Производител

EC REP

(US) - Authorised Representative
(F) - Représentant agréé
(E) - Representante autorizado
(I) - Distributore autorizzato
(D) - Bevollmächtigter
(P) - Representante Autorizado
(S) - Auktoriserad representant
(DK) - Autoriseret repræsentant
(GR) - Εξουσιοδοτημενος αντιπροσωπος
(PL) - Upoważniony Przedstawiciel
(LT) - Įgaliotasis atstovas
(H) - Meghatalmazott Képviselő
(EST) - Volitatud esindaja
(SK) - Autorizovaný zástupca
(CZ) - Zplnomocněný zástupce
(N) - Autorisert representant
(RO) - Reprezentant autorizat
(BG) - Упълномощен представител

LOT

(US) - Batch code
(F) - Code du lot
(E) - Código de lote
(I) - Codice del lotto
(D) - Chargen-Bezeichnung
(P) - Código do lote
(S) - Batchnr
(DK) - Batchkoden
(GR) - Κωδικας παρτιδας
(PL) - Numer serii
(LT) - Serijos numeris
(H) - Gyártási szám
(EST) - Partii kood
(SK) - Číslo šarže
(CZ) - Číslo šarže
(N) - Partikode
(RO) - Număr de lot
(BG) - Партиден номер

(US) - Expiry date YYYY/MM/DD
(F) - Date de peremption AAAA/MM/JJ
(E) - Estable hasta AAAA/MM/DD
(I) - Da utilizzare prima del AAAA/MM/GG
(D) - Verwendbar bis JJJJ/MM/TT
(P) - Data de expiração AAAA/MM/DD
(S) - Utgångsdatum ÅÅÅÅ/MM/DD
(DK) - Anvendes før ÅÅÅÅ/MM/DD
(GR) - Ημερομηνια ληξης YYYY/MM/DD
(PL) - Data ważności YYYY/MM/DD
(LT) - Galioja iki YYYY/MM/DD
(H) - Szavatossági idő ÉÉÉÉ/HH/NN
(EST) - Aegumistähtaeg AAAA/KK/PP
(SK) - Použiteľné do RRRR/MM/DD
(CZ) - Datum exspirace RRRR/MM/DD
(N) - Utløpsdato ÅÅÅÅ/MM/DD
(RO) - Data expirarii AAAA/LL/ZZ
(BG) - Срок на годност година/месец/ден

(US) - Storage temperature limitation
(F) - Limites de températures de stockage
(E) - Temperatura límite
(I) - Limiti di temperatura di conservazione
(D) - Lagertemperatur
(P) - Limites de temperatura de armazenamento
(S) - Temperaturbegränsning
(DK) - Temperaturbegrænsning
(GR) - Περιορισμος θερμοκρασιας αποθηκευσης
(PL) - Temperatura przechowywania
(LT) - Saugojimo temperatūriniai apribojimai
(H) - Tárolási hőmérsékleti határok
(EST) - Piirangud säilitustemperatuurile
(SK) - Skladovacia teplota od do
(CZ) - Teplotní rozmezí od do
(N) - Oppbevaringstemperatur
(RO) - Limitele de temperatură la stocare
(BG) - Температурни граници на съхранение

(US) - Consult Instruction for use
(F) - Consulter le mode d'emploi
(E) - Consulte las instrucciones de uso
(I) - Consultare le istruzioni per uso
(D) - Siehe Gebrauchsanweisung
(P) - Consulte o folheto informativo
(S) - Se bruksanvisningen
(DK) - Se instruktion før brug
(GR) - Συμβουλευθειτε τις οδηγιες χρησης
(PL) - Sprawdź instrukcję
(LT) - Ieškokite informacijos vartojimo instrukcijoje
(H) - Olvassa el a használati utasítást
(EST) - Kasutamisel vaata instruktsiooni
(SK) - Katalógové číslo
(CZ) - Viz návod k použití
(N) - Se bruksanvisninger
(RO) - Consultati prospectul de utilizare
(BG) - Виж инструкцията за употреба

(US) - The other languages which are required in conformity to the European Directive can be obtained from your local Bio-Rad agent.

(F) - Les autres langues requises par la Directive Européenne sont disponibles auprès de votre représentant Bio-Rad local.

(E) - Los otros idiomas que se requieren para la conformidad de la Directiva Europea puede ser obtenida en su oficina local Bio-Rad.

(I) - Le altre lingue che sono richieste in conformità con le Direttive Europee possono essere ottenute dal locale agente Bio-Rad.

(D) - Die anderen Sprachen, die in Übereinstimmung mit der europäischen IVD Direktive benötigt werden, erhalten Sie über Ihre lokale Bio-Rad Niederlassung.

(P) - As restantes línguas, obrigatórias em conformidade com a Directiva Europeia, podem ser obtidas através da subsidiária Bio-Rad mais próxima de si.

(S) - Övriga språk som krävs i enlighet med EG-direktivet kan erhållas från din lokala Bio-Rad-representant.

(DK) - De øvrige sprog som kræves i henhold til EU direktiv kan fås ved henvendelse til den lokale Bio-Rad leverandør.

(GR) - Τις υπολοιπες γλωσσες που απαιτουνται για συμμορφωση στην ευρωπαικη οδηγια μπορειτε να τις προμηθευθειτε απο τον τοπικο σας αντιπροσωπο Bio-Rad.

(PL) - Tłumaczenie w innych językach które są wymagane w Dyrektywie Unijnej może być otrzymane od lokalnego przedstawiciela firmy Bio-Rad.

(LT) - Vertimus, reikalingus pagal Europos sąjungos direktyvos reikalavimus, į kitas kalbas galite gauti iš vietinio Bio-Rad atstovo.

(H) - A leírás az Európai Irányelv által előírt egyéb nyelveken hozzáférhető a Bio-Rad helyi kirendeltségeinél.

(EST) - Teised vastavalt Euroopa Direktiivile nõutavad keeled on saadaval kohaliku Bio-Radi edasimüüja käest.

(SK) - Ostatné jazykové verzie, ktoré sú vyžadované v zhode s Európskou direktívou, možno obdržať od vášho lokálneho zástupcu Bio-Rad.

(CZ) - Další jazykové verze vyžadované ve shodě s evropskou direktivou jsou k dispozici u lokálního zastoupení firmy Bio-Rad.

(N) - Øvrige språk som kreves i henhold til EU-direktivet, fås fra din lokale Bio-Rad-representant.

(RO) - Alte traduceri cerute în conformitate cu Directiva Europeană se pot obține de la Reprezentanța Bio-Rad locală.

(BG) - Останалите езици, които се изискват съгласно Европейската Директива, могат да Ви бъдат предоставени от локалния представител на Био-Рад.

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