BIO-RAD

RABBIT PLASMA 56352

FOR COAGULASE TEST

IVD

1- INTENDED USE

Freeze-dried rabbit plasma is used for the detection of free coagulase produced by *Staphylococcus aureus*.

2- PRINCIPLE

The production of by *Staphylococcus aureus* induces coagulation of the plasma, resulting in formation of a coagulation pellet.

3- HOW SUPPLIED

- **Presentation**

LABEL		REAGENTS
R1	Rabbit Plasma	1 x 10 ml vial of freeze-dried rabbit plasma
R2	Diluent	1 x 10 ml ampoule of diluent (sodium oxalate)

- **Storage**

Freeze-dried powder: at +2-8°C until the expiry date indicated on the bottle and the kit.

After reconstitution: 48 hours at +2-8°C.

4- INSTRUCTIONS

a) Preparation of the plasma

-Take exactly 10 ml of solvent using a sterile pipette.

- Under sterile conditions, add the 10 ml of solvent directly to the vial of freeze-dried rabbit plasma.
- Shake gently to ensure dissolution while avoiding the formation of bubbles.

b) Preparation of the specimen

- From a culture of the strain to be examined, perform a subculture in Staphylocoagulase broth (code 53544) or standard nutrient broth (*). Incubate for 18 hours at 37°C.
- Mix 0.5 ml of reconstituted plasma and 0.5 ml of culture in a haemolysis tube. Incubate the mixture for 24 hours at 37°C.

(*) Some non-inoculated standard broth preparations mixed with rabbit plasma can induce coagulation of this plasma. A preliminary broth-plasma control test must therefore be performed when Staphylocoagulase broth is not used.

c) Expected results

Strains of *Staphylococcus aureus* induce coagulation of rabbit plasma over a time interval ranging from half an hour to 24 hours. The plasma is generally totally solidified, allowing the tube to be inverted. A less compact clot visible before the 24th hour must be considered to be positive.

5- PERFORMANCE/QUALITY CONTROL OF THE TEST

- Appearance of the freeze-dried powder: clear **beige-pink**.
- The growth performances of rabbit plasma are verified with the following strains:

STRAINS	COAGULATION RESULT AFTER 24 hours at 37°C
Staphylococcus aureus ATCC 25923	+
Staphylococcus aureus ATCC 6538P	+
Staphylococcus saprophyticus ATCC 15305	-
Staphylococcus epidermidis ATCC 12228	-

6- 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.

7- LIMITS OF USE

The medium must be observed each hour for the first 4 hours, as some strains of *S. aureus* produce fibrinolysin, which lyses the zone of coagulation. After 24 hours, this fibrinolysis reaction can induce a false-negative result.

CE
- CE marking (European directive 98/79/CE on in vitro diagnostic medical devices)
- Marquage CE (Directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro)
- Marcado CE (Directiva europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro)
- EG Markierung (Europäische Richtlinie 98/79/EG über In-vitro-Diagnostika)
- Marchiatura CE (Direttiva europea 98/79/CE relativa ai dispositivi medico-diagnostici in vitro)
- Marcação CE (Directiva europeia 98/79/CE relativa aos dispositivos médicos de diagnóstico in vitro)
- CE-märkning (Europa direktiv 98/79/EG om medicintekniska produkter lör in vitro-diagnostik)
- CE-mærkningen (Europa direktiv 98/79/EF om medicinsk udstyr til in vitro-diagnostik)

IVD
- For *in vitro* diagnostic use
- Pour diagnostic *in vitro*
- Para diagnóstico *in vitro*
- *In vitro*-Diagnostikum
- Per uso diagnostico *in vitro*
- Para uso em diagnóstico *in vitro*
- *In vitro* diagnostik
- *In vitro* diagnose

REF
- Catalogue number
- Référence catalogue
- Número de catálogo
- Bestellnummer
- Numero di catalogo
- Número de catálogo
- Katalognummer
- Katalognummer


- Manufacturer
- Fabricant
- Fabricante
- Hersteller
- Produttore
- Fabricante
- Tillverkad av
- Fremstillet af

EC REP
- Authorised Representative
- Représentant agréé
- Representante autorizado
- Bevollmächtigter
- Distributore autorizzato
- Representante Autorizado
- Auktoriserad representant
- Autoriseret repræsentant

LOT
- Batch code
- Code du lot
- Código de lote
- Chargen-Bezeichnung
- Codice del lotto
- Código do lote
- Batch nr.
- Batchkoden


- Expiry date YYYY/MM/DD
- Date de peremption AAAA/MM/JJ
- Estable hasta AAAA/MM/DD
- Verwendbar bis JJJJ/MM/TT
- Da utilizzare prima del AAAA/MM/GG
- Data de expiração AAAA/MM/DD
- Utgångsdatum År/Månad/Dag
- Anvendes før ÅÅÅÅ/MM/DD


- Storage temperature limitation
- Limites de températures de stockage
- Temperatura limite
- Lagerungstemperatur
- Limiti di temperatura di conservazione
- Limites de temperatura de armazenamento
- Temperaturbegränsning
- Temperaturbegrænsning


- Consult Instruction for use
- Consulter le mode d'emploi
- Consulte la instrucción para el uso
- Siehe Gebrauchsanweisung
- Consultare le istruzioni per uso
- Consulte o folheto informativo
- Se instruktionsanvisning vid användning
- Se instruktion før brug

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

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

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

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

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

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

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

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

Οι υπόλοιπες γλώσσες που απαιτούνται από την Ευρωπαϊκή Οδηγία διατίθενται στον τοπικό αντιπρόσωπο Bio-Rad.

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