Instructions for use

NADAL® Rose Bengale

Agglutination Slide Test

REF 795030

IVD

Version 1.0

2011-07-18

nal von minden GmbH
Friedenstr. 32
D-93053 Regensburg

nal von minden GmbH
Carl-Peschken-Str. 9
D-47441 Moers

nal von minden GmbH
Laan van Waalhaven 305
NL-2497 Den Haag

www.nal-vonminden.de
info@nal-vonminden.de

NADAL® Rose Bengale *Agglutination Slide Test* (100 tests)

Art. No. 795030

1. Intended Use

Qualitative determination of antibodies anti-Brucella.

2. Clinical Significances

The diagnostic of Brucella may be assessed either by microorganism isolation in blood or stools, or by titration of specific antibodies in the patient serum. The reagent, because of its formulation in an acid buffer, is reactive with both IgG and IgM antibodies and very useful for the diagnosis of chronic individuals showing a high level of IgG antibodies, difficult to be detected by the reference tube method (Wright).

3. Principle of the Test

The Rose Bengal is a slide agglutination test for the qualitative and semi-quantitative detection of antibodies anti-Brucella in human and animal serum. The stained bacterial suspension agglutinates when mixed with samples containing specific IgG or IgM antibodies in the patient sample.

4. Reagents and Materials Supplied

Rose Bengal White cap	*Brucella abortus* suspension, strain S99, in lactate buffer 1 mol/L, phenol 5 g/L, Rose Bengal, pH 3.6
Control + Red cap	Animal serum, with an antibody anti- *Br.abortus* concentration ≥ 50 IU/mL. Sodium azide 0.95 g/L.
Control – Blue cap	Animal serum. Sodium azide 0.95 g/L.

100 tests:
- 2.5 mL Rose Bengal
- 1 mL Control +
- 1 mL Control -
- 8 x 6 disposable slides

5. Additional Required Materials

Mechanical rotator with adjustable speed at 80-100 r.p.m.

6. Storage & Stability

All reagents are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could affect the functionality of the test.

Reagents deterioration: Presence of particles.

7. Warnings and Precautions

- Phenol: Toxic (T) R24/25: Toxic in contact with skin and if swallowed. R34: Causes burns. S28.2: After contact with the skin, wash immediately with plenty of water. S45: In case of accident, seek medical advice immediately.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

8. Specimen Collection and Preparation

Specimen Storage

Fresh serum. Stable 8 days at 2-8ºC or 3 months at –20ºC.
Samples with fibrin should be centrifuged before use.
Do not use highly hemolized or lipemic samples.

9. Procedure of the Test

Calibration

The Rose Bengal sensitivity is calibrated against the 2º International Preparation of anti-*Brucella abortus* from NIBS (UK)(WHO).

Qualitative method

1) Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
1) Place 50 µL of the sample and one drop of each positive and negative control into separate circles on the slide test.
2) Swirl the R. Bengal reagent gently before use and add one drop next to the sample to be tested.
3) Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
4) Place the slide on a mechanical rotator at 80-100 r.p.m. for 4 minutes. False positive results could appear if the test is read after two minutes.

Semi-quantitative method

1) Make serial two fold dilutions of the sample in 9 g/L saline solution.
2) Proceed for each dilution as described in the qualitative method.

10. Interpretation of the Results

Examine the slide macroscopically for the presence or absence of visible agglutination immediately after removing it from the rotator.
The presence of agglutination indicates an antibody anti-Brucella concentration equal or greater than 25 IU/mL.
The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

Calculations

The approximate antibody concentration in the patient sample is calculated as follows:

25 x anti-Brucella Titer = IU/mL

Reference Values

Up to 25 IU/mL.
Each laboratory should establish its own reference range.rebum.

11. Quality Control

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as to create a comparative pattern for a better result interpretation.s

12. Limitations

Interferences

Hemoglobin (10 g/L), lipemia (10 g/L) and rheumatoid factors (300 IU/mL) do not interfere. Bilirrubin interferes at 2.5 mg/dL. Other substances may interfere[5].

13. Performance Characteristics

1) *Analytical sensitivity:* 25 (± 5) IU/mL, considering the described assay conditions
2) *Prozone effect:* No prozone effect was detected up to 1000 IU/mL.
3) *Diagnostic sensitivity:* 100 %.
4) *Diagnostic specificity:* 98 %.

14. References

1) Young E J. Clinical Infectious Diseases 1995; 21: 283-290.
2) Alton GC. Techniques for Brucellosis Laboratory INRA Paris, 1988.
3) Ariza J. Current Opinion in Infectious Diseases 1996; 9: 126-131.
4) Comité mixto FAO/OMS de expertos en Brucelosis. WLD Health Org Tech Rep Ser 1958; 148: 1-60.
5) Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

Ref.: 2011-07-20 VP

Symbol	English	Deutsch	Français	Nederlands	Español	Italiano
	Consult instructions for use	Gebrauchsan-weisung beachten	Consulter les instructions d'utilisation	Gebruiksaanwij-zing	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conform Europese richtlijnen	Conformidad europea	Conformità europea
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	In vitro diagnostisch gebruik	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
REF	Catalogue number	Katalog-Nr.	Numéro de catalogue	Catalogus nummer	Número de catálogo	Numero di Catalogo
LOT	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Lot nummer	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Geschikt voor <n> tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungs-temperatur	Température de conservation	Opslag temperatuur	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthalt-barkeitsdatum	Date limite d'utilisation	Houdbaarheids datum	Fecha de caducidad	Data di scadenza
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Cont.	Content	Inhalt	Conditionnement	Inhoud	Contenido	Contenuto

Symbol	Polski	Suomi	Portugues	Dansk	Svenska	Ελληνικά
	Patrz: ulotka informacyjna	Katso käyttöohjeet	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisning en	Εγχειρίδιο χρήστη
CE	Znak zgodności CE	CE-merkitty	Conformidade com as normas europeias	Europaeisk overensstemm else	Europeisk överensstämm else	Ευρωπαϊκή Συμμόρφωση
IVD	Tylko do użytku in-vitro	In vitro-diagnostiikka	Diagnóstico in vitro	In vitro diagnostik	In vitro diagnostik	in vitro διαγνωστικό
REF	Numer katalogowy	Luettelo-numero	Catálogo n.º	Katalognummer	Katalognummer	Αριθμός καταλόγου
LOT	Numer serii	Eränumero	No do lote	Lot nummer	Batchnummer	Αριθμός Παρτίδος
	Wystarszajonce na "n" powturzeń	Sisältää tarvikkeet "n" testiin	Contém o suficiente para <n> testes	Indeholder tilsttrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura przechowywani a	Säilytys-lämpötila	Temperatura de conservação	Opbevarings-temperatur	Förvaringstemp ratur	Θερμοκρασία αποθήκευσης
	Data ważności	Viimeinen käyttöpäivä	Prazo de validade	Udløbsdato	Utgångsdatum	Ημερομηνία λήξης
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nal von minden GmbH
Friedenstr. 32
D-93053 Regensburg
Fon: +49 (941)29010-0
Fax: +49 (941) 29010-50

nal von minden GmbH
Carl-Peschken-Str. 9
D-47441 Moers
Fon: +49 (2841) 99820-0
Fax: +49 (2841) 99820-1

Geschäftsführer:
R. Meißner, S. von Minden, T.Zander
Internet: www.nal-vonminden.de
E-Mail: info@nal-vonminden.de
FreeFax: (0800) 86 46 336

Registergericht Kleve
Handelsregister-Nr.: HRB 56 79
Steuer-Nr.: 119/5743/0964

NOTES:

NOTES:

CONTACTS:

www.nal-vonminden.com
info@nal-vonminden.de

Germany-Team:
Regensburg
Tel: +49 (941) 290 10 0
Fax: +49 (941) 290 10 50

Moers
Tel: +49 (2841) 99820-0
Fax: +49 (2841) 99820-1

Austria-Team:
Tel: +49 (0) 941 290 10 38
Free Tel: 0800 291 565
Fax: +49 (0) 290 10 50
Free Fax: 0800 298 197

UK & Ireland-Team:
Tel: +49 (0) 290 10 35
Free Tel –UK: 0808 234 1237
Free Tel – IRE: 1800 555 080
Fax: +49 (0) 290 10 50
Free Fax:

Spain-Team:
Tel: +49 (0) 941 280 963 80
Free Tel: 900 938 315
Fax: +49 (0) 941 290 10 50
Free Fax: 900 984 992

France-Team:
France Tel: 0800 915 240
France Fax: 0800 564 720
Swiss Tel: 0800 564 720
Swiss Fax: 0800 837 476
Belgium Tel: 0800 718 82
Belgium Fax: 0800 747 07
Lux. Tel: 800 211 16
Lux. Fax: 800 261 79

Poland-Team:
Tel: +49 (0) 941 290 10 20
Free Tel: 00 800 491 15 95
Fax: +49 (0) 941 290 10 50
Free Fax: 00 800 491 15 94

Italy-Team:
Tel: +49 (0) 941 290 10 34
Fax: +49 (0) 941 290 10 50

Netherlands-Team:
Tel: +31 (0) 30 75 600
Free Tel: 0800 0222 890
Fax: +31 (0) 70 30 30 775
Free Fax: 0800 024 9519

ELISA - Sales Lab Team:
Tel: +49 (941) 290 10 40
Fax: +49 (941) 290 10 50

nal von minden GmbH
Carl-Peschken-Straße 9
47441 Moers
Germany

www.nal-vonminden.com