SYMBOL DESCRIPTIONS
DESCRIPCIÓN DE LOS SÍMBOLOS
DESCRIZIONE DEI SIMBOLI

Expiration date
Date d'expiration
Fecha de caducidad
Prazo de validade
Data di scadenza
Termin ważności

SN

Serial Number
Numéro de série
Número de serie
Número de série
Numero di serie
Numer seryjny

LOT

Batch Code
Code du lot
Código de lote
Código do lote
Numero di lotto
Kod partii

Manufacturer
Fabricant
Fabricante
Fabricante
Produttore
Wytwórca

IVD

In vitro diagnostic medical device
Dispositif médical de diagnostic *in vitro*
Producto sanitario para diagnóstico *in vitro*
Dispositivo médico para diagnóstico *in vitro*
Dispositivo medico veterinario per la diagnostica *in vitro*
Wyrób medyczny do diagnostyki *in vitro*

DESCRIPTIONS DES SYMBOLES
DESCRIÇÃO DOS SÍMBOLOS
OPISY SYMBOLI

Storage temperature range
Intervalle de températures de conservation
Intervalo de temperaturas de conservación
Intervalo de temperaturas de conservação
Intervallo della temperatura di conservazione
Zakres temperatury przechowywania

CONTROL +

Postive control serum
Sérum de contrôle positif
Suero control positivo
Soro de controle positivo
Siero di controllo positivo
Dodatnia kontrola

CONTROL -

Negative control serum
Sérum de contrôle négatif
Suero control negativo
Soro de controle negativo
Siero di controllo negativo
Ujemna surowica kontrolna

Consult instructions for use
Consulter la notice d'utilisation
Consultar las instrucciones de uso
Consulte as instruções de utilização
Consultare le istruzioni per l'uso
Sprawdź w instrukcji obsługi

EC REP

Authorized Representative in the European Community
Mandataire dans la Communauté européenne
Representante autorizado en la Comunidad Europea
Mandatário na Comunidade Europeia
Rappresentante autorizzato nella Comunità Europea
Upoważniony przedstawiciel we Wspólnocie Europejskiej

Equine Infectious Anemia Virus Antibody Test Kit

AGID-EIA

I. INTRODUCTION

The agar gel immunodiffusion (AGID) test for the diagnosis of Equine Infectious Anemia (EIA) was described by Coggins and Norcross, *Cornell Veterinarian*, April 1970. The test has proven to reliably diagnose infection by detecting specific antibody against EIAV in the serum of infected horses.

II. TEST PRINCIPLES

The immunodiffusion test is based upon the concurrent movement of antigen and corresponding specific antibody toward each other in an agar gel, forming a visible precipitin line. Making use of this principle, the AGID test can reliably detect specific antibody that is formed after one to four weeks of infection with the EIA virus.

AGID-EIA uses a highly purified recombinant protein from the EIA virus which will form a specific line of identity with infected serum antibody. No precipitin lines will form if the serum is negative for EIAV.

III. KIT CONTENTS

EIA Antigen (Bottle A) ..... 1 vial
EIA Positive Control Serum (Bottle B) ..... 3 vials
EIA Negative Control Serum (Bottle C). ..... 1 vial
Package insert with instructions for conducting the test.

IV. PRECAUTIONS

For veterinary use only. Store contents of kit at 2 °C - 7 °C. Antigen and accompanying antiserum have been standardized and should be used together. Do not allow reagents to stand at room temperature for excessive periods of time while performing tests. Handle all reagents and equipment as if capable of transmitting EIA. Burn all containers and all unused contents. Autoclave all disposable test components and test specimens after use. Negative control, positive control, and antigen contain Amphotericin B, Penicillin G, Streptomycin, Gentamycin and sodium azide as preservatives. The negative control is to be used in place of a test serum. DO NOT PLACE NEGATIVE CONTROL SERUM IN THE POSITIVE CONTROL SERUM WELL.

V. SPECIMEN INFORMATION

Use only horse serum for test specimens. Specimens may be stored at 2 °C - 7 °C for up to five days. If longer storage is desired, store at –20 °C. The presence of gross turbidity, hemolysis or bacterial growth may interfere with the performance and accuracy of the test.

VI. TEST PROCEDURE

A. Preparation of Agar Gel

1. Borate Buffer is prepared by mixing:
   2 g Sodium Hydroxide (NaOH)
   9 g Boric Acid (H_3BO_3)
   1 liter distilled water
   The resulting pH should be adjusted to 8.6 ± 0.2.

2. A one percent solution of Noble agar is prepared in the borate buffer and dissolved by either of two methods.
    a. Boil the suspension to dissolve the agar and autoclave for seven minutes.
    b. Microwave agar solution for a total of 3 minutes at 30 second intervals or until agar dissolves.
3. Add 15 ml of agar to a 100 mm diameter petri dish.
4. Plates are cooled for 1 hour at room temperature and then stored at 2 °C - 7 °C. If uncut, plates can be stored up to one week.

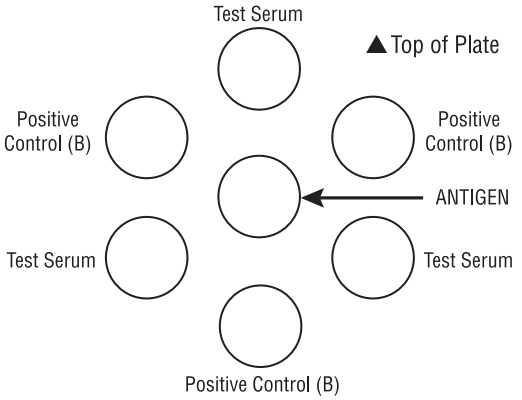
B. Cutting Wells in Agar

1. A seven-well pattern is used with one center well encircled by 6 wells. The wells are 2.4 mm apart and 5.3 mm in diameter.
2. Wells are cut while the agar is cold and the same day as used. Remove the agar plugs and leave lids ajar for 30 minutes before adding reagents and serum samples. Any remaining moisture in the wells should be suctioned out or allowed to evaporate.

C. Filling Wells and Incubation of Agar Plates
NOTE: THE EIA NEGATIVE CONTROL (BOTTLE C) SHOULD BE RUN IN AT LEAST ONE WELL FOR EVERY GROUP OF PLATES. IT SHOULD BE PIPETTED INTO A TEST WELL IN PLACE OF A TEST SERUM.

1. Fill each alternate outside well (see diagram 1) with one of the three test sera (or the kit negative control) but without overflowing onto the agar surface. Use a separate disposable pipette or pipette tip for each sample.
2. Fill the center well with purified EIA Antigen (Bottle A) in the same manner.
3. Fill the three remaining outside wells with EIA Positive Control Serum (Bottle B) in the same manner.
4. Incubate plates for 24 - 48 hours at room temperature in a moist chamber.

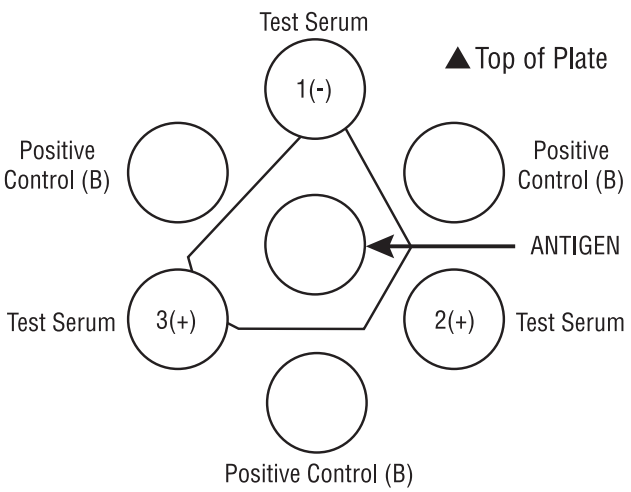
Diagram 1
PATTERN



VII. INTERPRETATION OF RESULTS (SEE DIAGRAM 2)

1. Negative – Control lines continue into the test serum well without bending or with a slight bend towards the antigen well.
2. Positive – Control lines join with and form a continuous line with the line between the antigen and test serum.
3. Weak Positive – Control lines bend slightly towards the antigen well and away from the positive control serum well but do not form a complete line between antigen and test serum.
4. Very strong positive – Control lines turn towards the antigen well and away from the positive control serum well but do not form a complete line between antigen and test serum.
5. Weak immunodiffusion reactions may be due to the following:
   a. Foals nursed by infected mares may produce positive results. The foal should be retested at 6 months of age to determine whether it is negative. If a mare is negative her positive foal should be considered infected.
   b. Weak positives have been observed during the incubation period of EIA. If a second sample is obtained 2 to 3 weeks later, the reaction should be stronger.
   c. Inapparent carriers that have no clinical signs of EIA for long periods of time may have weak reactions in the AGID. In these cases, retesting rarely results in a change in the strength of the reaction.
6. Any questionable sample should be sent to the National Veterinary Services Laboratory (NVSL) for verification.

Diagram 2



VIII. CONTROLS

EIA Positive Control Serum (Bottle B) –

If the positive control serum included in the kit does not react by forming a precipitin line with the EIA antigen (Bottle A), do not use the kit. Please contact Zoetis Veterinary Investigations Product Support (VMIPS) team at 1-800-366-5288 with questions and comments.

EIA Negative Control Serum (Bottle C) –

The negative control can be used as a comparison when testing weak reacting samples. If the negative control produces any precipitin line with the EIA antigen reagent, do not use the kit. Please contact Zoetis Veterinary Information & Product Support (VMIPS) team at 1-800-366-5288 with questions and comments.

VLN 190/PCN 5515.21
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EC	REP

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