

immunocard STAT![®]

C. difficile GDH-AB

EXTERNAL CONTROL SET

External Control Set for Immunocard STAT! C. difficile GDH-AB

REF 750501

IVD

INTENDED USE

Immunocard STAT! C. difficile GDH-AB External Control Set is a set including positive and negative controls to be used with the Immunocard STAT! C. difficile GDH-AB kit (Catalog# 750520), as part of a routine quality control program.

The GDH Positive Control contains glutamate dehydrogenase (GDH) purified from a culture of *C. difficile*, diluted in a buffered solution stabilized with proteins. The GDH Negative Control is a buffered solution including proteins. It contains sodium azide as preservative. These controls are intended to be used with **Immunocard STAT! C. difficile GDH-AB** for the GDH strip of the assay.

The 2A-B Cdiff Positive Control contains inactivated Toxin A (TcdA) and Toxin B (TcdB) purified from a culture of toxigenic *C. difficile* diluted in a buffered solution. The 2A-B Cdiff Negative Control is a buffered solution including proteins. It contains sodium azide as preservative. These controls are intended to be used with **Immunocard STAT! C. difficile GDH-AB** for the Toxins strip of the assay.

The External Controls are supplied ready to use.

SUMMARY AND EXPLANATION OF THE TEST

Quality control testing is performed to detect factors such as reagent deterioration, adverse environmental or test conditions, or variance in operator performance that can cause test errors. External control reagents, such as Immunocard STAT! C. difficile GDH-AB External Control Set, are reagents that are not built into the test system but are sampled and tested in the same manner as patient specimens.

BIOLOGICAL PRINCIPLES

Immunocard STAT! C. difficile GDH-AB External Control Set is used to create a known positive and negative control panel. The frequency with which a laboratory performs external controls will be affected by:

1. The proficiency level of the laboratory,
2. The laboratory's own internal requirements,
3. The requirements of the laboratory's accrediting agencies,
4. The number of new and different operators performing the test,
5. Whether a new kit lot is being added to testing,
6. Whether the kit lot is from a different shipment,
7. Whether deviations from the manufacturer's stated storage or handling conditions have occurred.

When unacceptable quality control test results are obtained, all test results should be considered invalid. QC test failures can mean that one of the reagents or components is no longer reactive at the time of use, the test was not performed correctly or that reagents or sample were not added.

REAGENTS/MATERIALS PROVIDED

The maximum number of tests obtained from this kit is listed on the outer box.

Reagents are supplied ready to use.

1. **Immunocard STAT! GDH Positive Control:** buffered solution containing glutamate dehydrogenase (GDH) purified from a culture of *C. difficile*.
2. **Immunocard STAT! GDH Negative Control:** buffered solution containing sodium azide as preservative.
3. **Immunocard STAT! 2A-B Cdiff Positive Control:** buffered solution containing inactivated Toxin A (TcdA) and Toxin B (TcdB) purified from a culture of toxigenic *C. difficile*.
4. **Immunocard STAT! 2A-B Cdiff Negative Control:** buffered solution containing sodium azide as preservative.

The Control Set expiry date is reported on reagent labels. Store at 2-8 C. Good Laboratory Practices must be enforced when manipulating controls. The GDH Positive Control is negative in the presence of common infectious agents since it is not derived from human culture cells and does not contain any human blood products. The 2A-B Cdiff Positive Control has been evaluated against the most high risk infectious agents (Hepatitis A&B, HIV) leading to a negative result. The negative controls do not contain any transmissible infectious agent. The reagents are ready to use.

MATERIALS NOT PROVIDED

1. **Immunocard STAT! C. difficile GDH-AB** kit (Catalog# 750520)
2. Vortex
3. Interval Timer
4. Micropipette capable of dispensing 170 µL

PRECAUTIONS

1. All reagents are for in vitro diagnostic use only.
2. This is a quality control reagent set and is used to evaluate the performance of **Immunocard STAT! C. difficile GDH-AB**. It is not directly used to test patient samples.
3. Store these reagents at 2-8 C when not in use. Do not freeze.
4. These reagents can be used with any **Immunocard STAT! C. difficile GDH-AB** kit lot number.

HAZARD AND PRECAUTIONARY STATEMENTS

There are no known hazards associated with this product.

QUALITY CONTROL TEST PROCEDURE

The test should be performed per applicable local, state, or federal regulations or accrediting agencies.

1. Let the positive and negative controls reach room temperature (19-27 C) for (at least 30 minutes before performing a test.
2. Use one **Immunocard STAT! C. difficile GDH-AB** card for each positive and negative control reagent to be tested for GDH and/or toxins. Remove each Test Card from its foil pouch. Label each card with the name of the control to be tested (Positive or Negative).
3. Using a new pipette tip, transfer 170 µL of the GDH Positive or Negative Control to the sample area of reaction strip for the detection of GDH located in the left side of an appropriately labelled card.
4. Using a new pipette tip, transfer 170 µL of the 2A-B Cdiff Positive or Negative Control to the sample area of reaction strip for the detection of TcdA and TcdB located in the right side of an appropriately labelled card.
5. Incubate the test for 15 minutes at room temperature.
6. At the end of incubation, read results as described in the section INTERPRETATION OF RESULTS of **Immunocard STAT! C. difficile GDH-AB** kit insert.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure.

LIMITATIONS OF THE PROCEDURE

The **Immunocard STAT! C. difficile GDH-AB External Control Set** is validated for use only with the **Immunocard STAT! C. difficile GDH-AB Rapid Assay**.

ITALIANO

immunocard STAT!®

C. difficile GDH-AB

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Set di Controllo Esterno per Immunocard STAT! C. difficile GDH-AB

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FINALITÀ D'USO

Il **Set di Controllo Esterno Immunocard STAT! C. difficile GDH-AB** è un set contenente controlli positivi e negativi da utilizzare con il kit **Immunocard STAT! C. difficile GDH-AB** (Numero di catalogo 750520), nell'ambito di un programma di controllo qualità di routine.

Il Controllo Positivo GDH contiene glutammato deidrogenasi (GDH) purificata da una coltura di *C. difficile*, diluita in una soluzione tamponata stabilizzata con proteine. Il Controllo Negativo GDH è una soluzione tamponata stabilizzata mediante proteine. Contiene sodio azide come conservante. Questi controlli devono essere utilizzati con **Immunocard STAT! C. difficile GDH-AB** per la striscia GDH del test.

Il Controllo Positivo 2A-B Cdiff contiene tossina A (TcdA) e tossina B (TcdB) inattivate e purificate da una coltura di *C. difficile* tossigenica diluita in una soluzione tamponata. Il Controllo Negativo 2A-B Cdiff è una soluzione tamponata contenente proteine. Contiene sodio azide come conservante. Questi controlli devono essere utilizzati con **Immunocard STAT! C. difficile GDH-AB** per la striscia Tossine del test.

I controlli esterni sono forniti pronti all'uso.

SOMMARIO E SPIEGAZIONE DEL TEST

I test di controllo qualità vengono eseguiti per rilevare fattori quali il deterioramento dei reagenti, condizioni ambientali o di analisi avverse o una varianza nelle prestazioni dell'operatore che possono causare errori di analisi. I reagenti di controllo esterno, come il Set di Controllo Esterno Immunocard STAT! C. difficile GDH-AB, sono reagenti non integrati nel sistema di analisi, bensì preparati e analizzati con le stesse modalità usate per i campioni dei pazienti.

PRINCIPI BIOLOGICI

Il **Set di Controllo Esterno Immunocard STAT! C. difficile GDH-AB** deve essere utilizzato per ottenere un pannello di controlli positivi e negativi noti. La frequenza con cui un laboratorio esegue i controlli esterni dipende dai seguenti fattori:

1. livello di competenza del laboratorio;
2. requisiti interni del laboratorio;
3. requisiti degli enti di accreditamento del laboratorio;
4. numero di nuovi operatori o di operatori diversi che eseguono il test;
5. apertura di un nuovo kit appartenente a un lotto diverso da quello in uso;
6. apertura di un nuovo kit pervenuto con una spedizione differente;
7. eventualità che si siano verificate deviazioni dalle condizioni di conservazione o di manipolazione indicate dal produttore.

Quando si ottengono risultati inaccettabili per i test di controllo qualità, tutti i risultati dei test devono essere considerati non validi. Il fallimento del test QC può significare che uno dei reagenti o componenti non è più reattivo al momento dell'uso, che il test non è stato eseguito correttamente o che non sono stati aggiunti reagenti o campioni.

REAGENTI/MATERIALI FORNITI

Il numero massimo di analisi eseguibili con questo kit è indicato sulla confezione esterna.

I reagenti vengono forniti pronti all'uso.

1. **Controllo Positivo Immunocard STAT! GDH:** soluzione tamponata contenente glutammato deidrogenasi (GDH) purificata da una coltura di *C. difficile*.
2. **Controllo Negativo Immunocard STAT! GDH:** soluzione tamponata contenente sodio azide come conservante.