CE

RIDASCREEN® Clostridium perfringens Enterotoxin Reference Controls

Art. No.: CRP0604

1. Intended use

For *in vitro* diagnostics.
RIDASCREEN® Clostridium perfringens Enterotoxin Reference Controls are external quality controls. They are suitable for use in the RIDASCREEN® Clostridium perfringens Enterotoxin ELISA.

2. Explanation

RIDASCREEN® Clostridium perfringens Enterotoxin Reference Controls are offered as separate articles. As external controls they are suitable, pursuant to legal requirements for internal laboratory quality controls, for testing the relevant parameters of commercially used test kits and for the quality assurance of internal laboratory processes.

3. Test Principle

RIDASCREEN® Clostridium perfringens Enterotoxin Reference Controls react specifically in the RIDASCREEN® Clostridium perfringens Enterotoxin ELISA (C0601). They are ready to use and are used analogously to the prediluted patient samples. The measured OD value of the reference controls must fulfil the requirements pursuant to point 9.

4. Materials provided

RIDASCREEN® Clostridium perfringens Enterotoxin Reference Controls are delivered as a ready to use set, consisting of two vials, each with 2 ml of reference material A and reference material B. They are to be stored between 2 and 8°C and can be used until the expiration date printed on the package

5. Materials required, but not provided

- RIDASCREEN® Clostridium perfringens Enterotoxin Reference Controls

6. Precautions

The reference material A contains recombinant Enterotoxin. However, they should be handled as if potentially infectious, pursuant to the national safety requirements.

7. Reagents and storage conditions

RIDASCREEN® Clostridium perfringens Enterotoxin Reference Controls are to be stored at 2-8 °C and used by the expiration date printed on the packaging. There is no quality guarantee after the expiration date.

8. Test procedure

RIDASCREEN® Clostridium perfringens Enterotoxin Reference Controls are ready to use and are used undiluted. It is recommended to pipette 0.5 ml of each reference material into a separate, clean test tube for testing on fully automatic instruments, such as DSX or Agility, and to transport these in the same way as patient samples. Once the test is complete, the rest of the reference controls are to be disposed of. Residual materials may not be poured back into the original vials.

9. Interpretation of results

Reference control A must be measured after the test is complete at 450 nm as well as through bichromatic measurement at 450/620 nm with a clear positive absorbance value greater than 0.5.
Reference control B must be regarded as negative both at 450 nm as well as through bichromatic measurement at 450/620 nm using the determined cut-off value. If these requirements are not fulfilled, an internal error analysis must ensure that the target values are reached during repetition. All measurements must be documented pursuant to internal lab quality assurance measures.

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