

**1. PRODUCT: Keul-o-test Clostridium Difficile Complete**

**Description:** Clostridium Difficile A + Clostridium Difficile B Combo Test Cat # KGST203  
**Quantity:** 404

**2. PHYSICAL INSPECTION: ok**
**3. REAGENT USED:**

|   | <b>Lot No:</b> | <b>Quantity:</b> | <b>Expiry</b> |
|---|----------------|------------------|---------------|
| a) Toxin A stick<br>Clostridium Difficile A | 23090-04       | 404              | 2012/05       |
| b) Toxin B stick<br>Clostridium Difficile B | 23090-04       | 404              | 2012/05       |
| c) Extraction solution                      | 19090-03       | 404 x 2 ml       | 2013/09       |

**4. RESULTS:**
**a) TOXIN A (Clostridium Difficile A)**

|                              | <b>Negative</b> | <b>Standard No1</b> | <b>Standard No2</b> | <b>Standard No3</b> | <b>Standard No4</b> |
|------------------------------|-----------------|---------------------|---------------------|---------------------|---------------------|
| <b>Expected after 15 min</b> | -               | -                   | + or -              | +                   | +                   |
| <b>Obtained after 15 min</b> | -               | -                   | -                   | +                   | +                   |

**b) TOXIN B (Clostridium Difficile B)**

|                              | <b>Negative</b> | <b>Standard No1</b> | <b>Standard No2</b> | <b>Standard No3</b> | <b>Standard No4</b> |
|------------------------------|-----------------|---------------------|---------------------|---------------------|---------------------|
| <b>Expected after 15 min</b> | -               | -                   | + or -              | +                   | +                   |
| <b>Obtained after 15 min</b> | -               | -                   | -                   | +                   | +                   |

**5. RETENTION SAMPLES:**

Retain 6 **Keul-o-test Clostridium Difficile Complete** tests as samples per each 6000 tests ordered quantity from each batch (under dessicated conditions) at room temperature until the expiration date.

**6. CONCLUSION:**

Approved      ok  
 Hold  
 Rejected



2010-09-26  
 Date

QM-Manager  
 Günter Keul