

**1. PRODUCT: Keul-o-test Clostridium Difficile Complete**
**Description:** Clostridium Difficile A + Clostridium Difficile B Combo Test Cat # KGST203

DIMDI Reg.-Nr.: DE/CA22/1116-134-IVD

**Quantity:** 303

**2. PHYSICAL INSPECTION:** ok

**3. REAGENT USED:**

	<b>Lot No:</b>	<b>Quantity:</b>	<b>Expiry</b>
a) Toxin A stick Clostridium Difficile A	27121	303	2013/08
b) Toxin B stick Clostridium Difficile B	27121	303	2013/08
c) Extraction solution	28041-02	303 x 2 ml	2014/04

**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


2012-01-06  
 Date

 QM-Manager  
 Günter Keul