

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: 404

2. PHYSICAL INSPECTION: ok

3. REAGENT USED:

	Lot No:	Quantity:	Expiry
a) Toxin A stick Clostridium Difficile A	09031	404	2012/11
b) Toxin B stick Clostridium Difficile B	09031	404	2012/11
c) Extraction solution	18021-01	404 x 2 ml	2014/02

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

	Negative	Standard No1	Standard No2	Standard No3	Standard No4
Expected after 15 min	-	-	+ or -	+	+
Obtained after 15 min	-	-	-	+	+

b) TOXIN B (Clostridium Difficile B)

	Negative	Standard No1	Standard No2	Standard No3	Standard No4
Expected after 15 min	-	-	+ or -	+	+
Obtained after 15 min	-	-	-	+	+

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


2011-03-13
 Date

 QM-Manager
 Günter Keul