Günter Keul GmbH
Von-Langen-Weg 10
D-48565 Steinfurt
Tel.: 02551/2097 Fax.: 02551/80883

Certificate of Analysis

Product Name: **StrepA (Swab)** DIMDI Reg.-Nr.: DE/CA22/1115-289-IVD
Catalog No.: **KGST109**
Date of Sampling: **2017-03-10**
Date of Analysis: **2017-03-10**
Expiry date: **2019-03**
Batch No.: **STA17030007**
Extraction reagent 1 Lot: **17020085, EXP: 2019-03**
Extraction reagent 2 Lot: **17020044-2, EXP: 2019-04**
Positive control Lot: **17020114, EXP: 2019-04**
Negative control Lot: **17020105, EXP: 2019-04**
Quantity: **8000 PCS**

OC Item		Standard & Criteria	Test Result	Conclusion
Physical	**Appearance**	Good	Good	Pass
Functional Performance:	**Positive Sample**	1E+07 org/ml:100% Positive	100% Positive	Pass
		2.5E+07 org/ml:100% Positive	100% Positive	Pass
	Positive Sample	100% Positive	100% Positive	Pass
	0.5% BSA-PBS	100% Negative	100% Negative	Pass
	Negative Sample	100% Negative	100% Negative	Pass

Conclusion: This batch of product met the QC standards.

QM-Manager
Günter Keul

2017-03-13
Date