

IO 09 - 010-V



CODE 91030

CODE 91176

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT RUBELLA IgG

LOT. 285

DATE OF TEST 03/01/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	2.496	
	CV%	7%	< 20%
2nd PLATE	OD 450 nm	2.641	
	CV%	4%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	2.434	
	CV%	5%	< 15%
2. BULK CONTROL date: 19/12/2023			
A) Average OD of Cut Off Calibrator	OD 450 nm	0.524	≥ 0.200
B) Index of Negative and Positive Sera		accepted	According to specification
C) Sensitivity with working calibrators		accepted	According to specification
3. CONTROL OF COMPLETE KIT date: 03/01/2024			
A) Substrate Blank	OD 450 nm	0.048	≤ 0.100
Calibrator 0 IU/ml	OD 450 nm	0.004	≤ 0,6 Cut-off
Calibrator 5 IU/ml	OD 450 nm	0.265	< Cut-off
Calibrator 10 IU/ml (Cut-off)	OD 450 nm	0.581	≥ 0.200
Calibrator 50 IU/ml	OD 450 nm	1.348	
Calibrator 100 IU/ml	OD 450 nm	2.293	
Calibrator 200 IU/ml	OD 450 nm	2.901	≥ 1.500
B) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.629	
	CV%	7%	≤ 15%
C) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 03.01.2024

Signed:

Released: Q.C.Manager