Certificate of Analysis

vircell MICROBIOLOGISTS

Product name	CHAGAS ELISA IgG+IgM
Catalogue Number	T1020
Lot Number	25ECHAT102
Expiry date	2027/03

Kit contents	Lot Number	Expiry date	Specifications	Lot result
VIRCELL CHAGAS PLATE	25ECHA101	2027/07		
VIRCELL SERUM DILUENT	25EDB008	2027/11		
VIRCELL IgG+IgM POSITIVE CONTROL	25ECHAT002	2027/03	OD > 0.90	2.97
VIRCELL IgG+IgM CUT OFF CONTROL	25ECHAT202	2027/03	0.55 < OD < 1.50	1.08
VIRCELL IgG+IgM NEGATIVE CONTROL	25ECHAT052	2027/07	OD < 0.50	0.02
VIRCELL IgG+IgM CONJUGATE	25ECHAT302	2027/03		
VIRCELL TMB SUBSTRATE SOLUTION	24ES002	2028/04		
VIRCELL STOP REAGENT	25EP001	2027/07		
VIRCELL WASH BUFFER (20x)	25EL015	2027/11		

This is to certify that the above kit performs in accordance with the Quality Control specifications of Vircell, S.L. and fulfils the essential requirements as established in Directive 98/79/CE and part of Regulation (EU) 2017/746. All human blood components have been tested and found to be non-reactive for HBsAg and antibodies to HCV, HIV 1 and HIV 2. Vircell, S.L. manufactures under ISO 9001 and ISO 13485 certified quality systems.

Q.C. Testing by

Position	Name	Date	Signature
Quality Control Department	Labrat Rodríguez, Rubén	18/07/2025	

AENOR GESTIÓN DE LA CALIDAD ISO 9001 AENOR GESTIÓN AMBIENTAL ISO 14001

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