COA-AD0171C,Rev F01 022724

CERTIFICATE OF ANALYSIS

I. Product Information:

Product name:	Chagas Ab Combo Rapid Test (Cassette)
Catalog No.:	AD0171C
Lot No.:	F1110W6F01D
Manufacture date:	2025-11-12
Expiration date:	2027-11-11
Sample diluent:	Catalog: SB-R0171, Lot: S017315-59, Exp.: 2028-07-14
Storage:	Room temperature (2-30°C)

II. Applicable Inspection and Evaluation of Specification:

1. Physical Inspection:

Test Criteria Description	Acceptance	Results
a. Label	Ac ≤ 5	0
b. Pouch	Ac ≤ 5	0
c. Capillary tubes	Ac ≤ 5	0
d. Insert	Ac ≤ 5	0
e. Sample diluent	Ac ≤ 5	0
f. Desiccant in the Pouch	Ac ≤ 5	0
g. Cassette in the Pouch	Ac ≤ 5	0
h. Label on the Cassette	Ac ≤ 5	0

Note: AC (Acceptance Number) is the maximum allowable defectives in a sample for the lot to be accepted based on the sampling plan.

2. **Performance Characteristic Inspection:**

Test Description		Acceptance Level		Criteria	Test Results
a.	Positivity	2 positive samples		Both positive	Both positive
		1 whole blood positive		Positive	Positive
b.	LOD	R0171-L1		Positive	Positive
		R0171-L2		Positive	Positive
		R0171-L3		Positive/Negative	Negative
c.	Negativity	20 negative samples		All negative	All negative
d.	Precision	10 replicates		Uniformed band	Uniformed band
e.	Sample diluent	SB-R0171		Negative	Negative
f.	Background	Female blood	10 replicates	Clear	Clear
		Male blood	10 replicates	Clear	Clear
g.	Specificity	100 clinical negative samples		⩾98%	100%
h.	Flow Rate	Completion of run in membrane		In 2 minutes	In 2 minutes

III. Comments:

All data are from Q.C. test unless otherwise indicated.

IV. Safety Certification:

There are no biohazard materials utilized in this product, no radioactive materials, no narcotic reagents, neither their derivatives, no virus neither their reagent, nor metabolic by-products.

V. Release of above information:

Released [√] Rejected [ ]

Sandy Liu

Sandy Liu(QA representative)

2025-11-20

Date