

Certificate of Analysis

This product has been tested and meets all Biolytical Quality Control functional specifications for releasing finished devices for distribution.

1 DEVICE INFORMATION			
Part Number	90-1041	Expiry Date (YYYY-MM-DD)	2022-06-05
Lot Number	1041210100	Storage	Store at 2°C to 30°C (35.6°F to 86°F)
Description	INSTI HIV SELF TEST	Date of Manufacture (YYYY-MM-DD)	2021-04-13

2 TEST RESULTS	
Test	Result (Pass/Fail)
HIV-1 Positive Panel	Pass
HIV Negative Panel	Pass
HIV-2 Positive Plasma	Pass
HIV Negative Whole Blood	Pass
Contrived HIV-1 Positive Whole Blood	Pass
HIV Low Positive Control	Pass

3 TEST COMPONENTS	
Component	Lot Number
Blotted Membrane Unit	801097210213
Colour Developer	801017210251
Sample Diluent	801016210222
Clarifying Solution	801018210120

14-Apr-2021

Date
(dd-MMM-yyyy)

Jiyeon Hong, QA Specialist

QA Approval



Declaration of Conformity

PRODUCT IDENTIFICATION

Product name	Model/number
INSTI HIV SELF TEST	Catalogue No.: 90-1041

MANUFACTURER

Name of company	Address	Representative
BioLytical Laboratories Inc.	406-13251 Delf Place, Richmond, BC V6V 2A2 Canada	Larisa Baesu

AUTHORIZED REPRESENTATIVE

Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP, The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax EmergoEurope@ul.com

REGISTRATION INFORMATION

Notified Body and ID #	CE certificate number
Presafe Denmark, 0543 (for HIV-1/HIV-2)	DGM-548 DGM-549

CONFORMITY ASSESSMENT

Device classification	Route to compliance
Class: Annex II List A	Annex IV of IVDD 98/79/EC Council Directive (for HIV-1/HIV-2)

BioLytical Laboratories Inc. declares that the above mentioned products comply with the Essential Requirements in Annex I of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices and Directive 98/79/EC as transposed in the national laws of the Members States.

COMPANY REPRESENTATIVE: Larisa Baesu

TITLE: QA Manager

SIGNATURE: 

DATE: 2020-10-21

YYYY-MM-DD

BioLytical Laboratories Inc.
Tel: +1-604-204-6784

#406-13251 Delf Place, Richmond
Fax: +1-604-244-8399

British Columbia, Canada, V6V 2A2
Email: customercare@biolytical.com