5-DIAGNOSTICS

Certificate of Analysis

5-ELISA Factor XI (Factor XI-AG), 6x16 tests

Product: 5D-55126

Lot #: 643318

Expiry: 12/2027

Storage: Upon receipt store all kit components between 2-8°C.

Specifications:

Lot Specific Calibrator Plasma Value: 0.81 IU/ml

Specification	Acceptance Criteria	Lot specific results		
		Kit 1	Kit 2	Kit 3
A-450 at 1/50 dilution	≥1.0, ≤2.5	2.380	2.120	2.316
Background Absorbance	≤0.125	0.055	0.050	0.046
R^2	≥0.990	0.992	0.993	0.997
Control Plasma A value	0.78-1.06 IU/ml	0.86 IU/ml	0.95 IU/ml	0.92 IU/ml
Control Plasma B value	0.18-0.26 IU/ml	0.21 IU/ml	0.23 IU/ml	0.21 IU/ml
FXI deficient plasma value	< 1%	<1%	<1%	<1%

Although this material was prepared with human plasma which was tested at source and found negative for HBsAg, syphilis and antibodies to HIV 1, HIV 2 and HCV and non-reactive for HIV-1 rNA and HCV rNA by FDA approved tests, it should be handled by personnel trained in the proper procedures for handling potential viral contaminants.

Caution: For Research Use Only. Not for In Vitro Diagnostic Use.

Authorization:

Marco Steiner
Operations Manager

Date: October 21, 2026