



Lot Number: 8120 **Manufacture Date:** 2017-12-04 **Shelf-Life/Expiration Date:** 2019-12-31

Product Name: FASC Position Marker Kit

REF 01-04-0042

Manufactured/Distributed By: Trinity Biotech

Storage Requirements: Store lyophilized material in original container at 2-8°C up to the expiration date. See Package Insert for instructions on storage of reconstituted, aliquot, and diluted materials.

Intended Use: FASC Position Marker is intended for *in vitro* diagnostic use in laboratory quality control program for the qualitative identification of FASC hemoglobin fractions.

Method of Analysis: Performance Testing
Standard: HPLC performance validation.
Result:

<u>Hemoglobin</u> <u>Fraction</u>	<u>RT</u>	<u>Retention Time</u> <u>Resolution™ High Resolution</u>	<u>RT</u>	<u>Retention Time</u> <u>GeneSys™ High Resolution</u>
F	1.658	At least 1.2 minutes	1.698	At least 1.2 minutes
A	4.075	At least 1.3 minutes after F	3.609	At least 1.3 minutes after F
S	5.753	At least 1.3 minutes after A	5.150	At least 1.3 minutes after A
C	7.770	At least 7.0 minutes	6.913	At least 6.8 minutes

Testing to Confirm Non-Reactivity for Common Pathogens

Standard: Verify test results or confirm certification that source material have been tested and found non-reactive for common pathogens, including HBsAG, HBc, HIV-1&2, HCV, HTLV 1&2, HIV 1&2-RNA, Syphilis, HBV-DNA.

Results: Testing certification confirmed to be negative/non-reactive for common pathogens.

Approval

Quality Manager:

Date:

12/6/2017

PH 12/6/17
MC 12/7/17