



**Lot Number:** 12090    **Manufacture Date:** 2021-05-18    **Shelf-Life/Expiration Date:** 2023-05-31

**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 Fraction</u>	<u>Retention Time</u>		<u>Retention Time</u>	
	<u>RT</u>	<u>Resolution™ High Resolution</u>	<u>RT</u>	<u>GeneSys™ High Resolution</u>
F	1.650	At least 1.2 minutes	1.885	At least 1.2 minutes
A	4.150	At least 1.3 minutes after F	3.868	At least 1.3 minutes after F
S	5.752	At least 1.3 minutes after A	5.368	At least 1.3 minutes after A
C	7.745	At least 7.0 minutes	7.018	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:

01 Jun 2021

*MSK 2021-06-02  
PH 01 Jun 21*