



FASC Position Marker Kit

REF 01-04-0042 **CONT** 2 x 1000µL FASC Position Marker

TRINITY BIOTECH
KANSAS CITY, MO 64132 USA
www.trinitybiotech.com

LOT 12090
2023-05-31

EC REP
Trinity Biotech plc
Bray, Co. Wicklow, Ireland
Tel: +353 1 276 9800
Fax: +353 1 276 9888



www.trinitybiotech.com

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For other languages, please contact your local distributor.

INTENDED USE

Hemoglobin FASC Position Marker is intended for in vitro diagnostic use in laboratory quality control program for the total hemoglobin and hemoglobin variants determination of hemoglobinopathies.

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SUMMARY AND EXPLANATION OF THE TEST

Recognition and presumptive identification of hemoglobin variants is useful in that many of these altered hemoglobins are associated with disorders of hemoglobin called hemoglobinopathies. The FASC Position Marker is prepared from stabilized whole blood hemolysates containing hemoglobins F, A, S, and C that are then combined and lyophilized to ensure stability. When reconstituted, each sample provides a clear, cherry red hemolysate. The material is used as a retention time marker for the known hemoglobins that it contains. It is also used to monitor the total system performance. Retention time ranges are provided to assure optimal system performance.

PRINCIPLE OF THE PROCEDURE

Utilizing a High Performance Liquid Chromatography (HPLC) system, hemoglobins are separated, quantitated and presumptively identified by comparison to reference peaks of Hb F, A, S and C. An ion-exchange column that has been equilibrated with respect to pH and ionic strength is used to separate the hemoglobin species.

REAGENTS / COMPONENTS

2 vials lyophilized FASC Position Marker
1000 µL FASC Position Marker after reconstitution
1 package insert

The FASC Position Marker contains a stabilizer. After reconstitution and dilution the FASC Position Marker should be used in the same manner as a patient hemolysate.

STORAGE AND STABILITY



Closed Container (Lyophilized): Lyophilized vials of FASC material stored at 2-8°C are stable until the expiration date indicated on the label.



Open Container (Reconstituted): Once reconstituted, the FASC material in tightly sealed containers are stable for up to 8 weeks when stored at 2-8°C.



Open Container (Aliquots): Aliquots of the undiluted reconstituted FASC material are stable for up to 1 year in tightly closed containers when stored at -20°C (-30 to -20°C).



In-Use (On Instrument): After final dilution, the FASC material is stable for up to 24 hours on instrument at room temperature (20 to 25°C).



DO NOT USE after the expiration date.

PRECAUTIONS



POTENTIALLY BIOHAZARDOUS MATERIAL

Human sourced materials were used in the manufacturing of this product. This product was found to be non-reactive for Hepatitis B surface antigen (HBsAg), antibodies to Hepatitis C (HVC), and antibodies to Human Immunodeficiency Viruses (HIV-1 and HIV-2), when tested by FDA cleared methods. No known test method can offer assurance that products derived from human blood will not transmit disease, and material should be handled as such.

CAUTION

For *In Vitro* Diagnostic Use ONLY

SAFETY GLASSES, GLOVES AND LAB COAT ARE RECOMMENDED WHEN USING THE TRINITY FASC POSITION MARKER MATERIAL.

DO NOT USE: If diluted sample turns dark brown.

PREPARATION PROCEDURE

RECONSTITUTION

- Remove the seal and stopper from the vial.
- Add 1000µL of 2 Diluent (**REF** 01-03-0056, or 01-03-0059) or GeneSys Diluent (**REF** 01-03-0019) to the vial.
- Allow the vial to stand for 15 minutes, then rotate gently until the material is completely dissolved.

DILUTIONS

Following the instructions below, dilute the reconstituted FASC Position Marker using diluent. Mix well.

System	Dilution Ratio	µL FASC:µL Diluent	Vial Type
<i>ultra</i> ² Resolution™	1:80	20:1580	Shell Vial or Crimp Top
<i>ultra</i> ² GeneSys™	1:80	20:1580	Shell Vial or Crimp Top

TEST PROCEDURE

After reconstitution and dilution of the FASC Position Marker, it should be analyzed in the same manner as patient samples.

RESULTS AND INTERPRETATION OF RESULTS

When assayed using the *High Resolution* assay of the *ultra*² Resolution software or GeneSys software, the results should be within the limits indicated below for the *ultra*² instruments:

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Vial **LOT** 12091

Hemoglobin	Resolution Retention Time	GeneSys Retention Time
F	At least 1.2 minutes	At least 1.2 minutes
A	At least 1.3 minutes after F	At least 1.3 minutes after F
S	At least 1.3 minutes after A	At least 1.3 minutes after A
C	At least 7.0 minutes	At least 6.8 minutes

Users of other methods should determine their own values.

LIMITATIONS

- This product should not be used past the expiration date.
- If there is evidence of microbial contamination, brown color or excessive turbidity in the reconstituted material, discard the vial

REFERENCES

- Ou, Clin Chem **39**, 820, (1993)
- Ou, Clin Chem **31**, 945, (1985)
- Ou, J Chromatogr **226**, 197, (1983)
- Rogers, Am J Clin Pathol **84**, 671, (1985)
- Wessels, Clin Chem **32**, 903, (1986)

ORDERING INFORMATION

Reference No.	Item	Quantity
01-04-0042	Kit, FASC Position Marker	2 x 1000µL FASC



Trinity Biotech
Kansas City, MO 64132 USA
Tel. 1 800-325-3424
Fax: 1 816-361-1974

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Trinity Biotech plc
Bray Co. Wicklow, Ireland
Tel. 353 1 2769800
Fax 353 1 2769888
www.trinitybiotech.com

