A2+F Control Material Kit

REF 01-04-0043 CONT 2 x A2+F Level I Control
2 x A2+F Level II Control

TRINITY BIOTECH
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LOT 12110

2023-05-31

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2 °C – 8 °C

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05-02-0023

INTENDED USE

Hemoglobin controls are intended for in vitro diagnostic use in laboratory quality control program for the quantitation of HbA2 and HbF. IVD

SUMMARY AND EXPLANATION OF THE TEST

Quantitation of HbF can be useful when evaluating pediatric patient samples for hemoglobinopathies and also for the evaluation of Hb variants and thalassemias in adults. The A2+F Control Material is prepared from stabilized whole blood hemolysates containing hemoglobins A, F, A2 and S that are then combined and lyophilized to ensure stability. When reconstituted, each sample provides a clear, cherry red hemolysate. It is also used to monitor the total system performance. Reference 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. The two levels of A2+F Controls are provided to allow for performance monitoring.

REAGENTS / COMPONENTS

2 vials lyophilized A2+F Level I Control Material
(Normal %F, Normal %A2)
2 vials lyophilized A2+F Level II Control Material
(Elevated %F, Elevated %A2, Normal %HbS)
300 µL each vial after reconstitution
1 Package insert

The Control Material contains a stabilizer. After reconstitution and dilution the Control Material should be used in the same manner as a patient hemolysate.

STORAGE AND STABILITY

Closed Container (Lyophilized): Lyophilized vials of A2+F Control material stored at 2-8°C are stable until the expiration date indicated on the label.

Open Container (Reconstituted): Once reconstituted, the A2+F Control material in tightly sealed containers are stable for up to 21 days when stored at 2-8°C.

Open Container (Aliquots): Aliquots of the undiluted reconstituted A2+F Control material are stable for up to 90 days in tightly closed containers when stored at -20°C (-30 to - 20°C).

In-Use (On Instrument): After final dilution, the A2+F control sample 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 A2+F CONTROL MATERIAL.

DO NOT USE: If diluted sample turns dark brown.

PREPARATION PROCEDURE

RECONSTITUTION

1. Remove the seal and stopper from the vial.
2. Add **300**µL of 2 Diluent (REF 01-03-0056, or 01-03-0059) or GeneSys Diluent (REF 01-03-0019) to the vial.
3. Allow the vial to stand for 10 minutes, then rotate gently until the material is completely dissolved.

DILUTIONS

Following the instructions below, dilute the reconstituted A2+F Control Material using Trinity Biotech Diluent (listed above). Mix well.

System	Dilution Ratio	µLControl:µL Diluent	Vial Type
***ultra*² Resolution™**	**1:120**	**15:1785**	**Shell Vial or Crimp Top**
***ultra*² GeneSys™**	**1:120**	**15:1785**	**Shell Vial or Crimp Top**

TEST PROCEDURE

After reconstitution and dilution of the A2+F Control Material, it should be analyzed in the same manner as patient samples.

RESULTS AND INTERPRETATION OF RESULTS

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

Kit LOT 12110 2023-05-31

*ultra*² Resolution™ Quick Scan Assay (Column REF 01-05-0015)

	$\bar{x}$ %F	RNG %F	$\bar{x}$ %A2	RNG %A2	$\bar{x}$ %S	RNG %S
Level I LOT 12111	1.7	0.7– 2.7	2.0	1.0– 3.0		
Level II LOT 12112	7.7	6.2– 9.2	5.5	4.4– 6.6	31.5	25.2– 37.8

*ultra*² Resolution™ High Resolution Assay (Column REF 01-05-0015)

	$\bar{x}$ %F	RNG %F	$\bar{x}$ %A2	RNG %A2	$\bar{x}$ %S	RNG %S
Level I LOT 12111	2.0	1.0– 3.0	2.6	1.6– 3.6		
Level II LOT 12112	7.8	6.2– 9.4	5.9	4.7– 7.1	30.9	24.7– 37.1

*ultra*² GeneSys™ High Resolution Assay (Column REF 01-05-0017)

	$\bar{x}$ %F	RNG %F	$\bar{x}$ %A2	RNG %A2
Level I LOT 12111	1.9	0.9– 2.9	2.6	1.6– 3.6
Level II LOT 12112	7.3	5.8– 8.8	6.0	4.8– 7.2

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

1. Ou, Clin Chem 39, 820, (1993)
2. Ou, Clin Chem 31, 945, (1985)
3. Ou, J Chromatogr 226, 197, (1983)
4. Rogers, Am J Clin Pathol 84, 671, (1985)
5. Wessels, Clin Chem 32, 903, (1986)

ORDERING INFORMATION

Reference No.	Item	Quantity
01-04-0043	Kit, A2+FControl Material	2 x A2+F Level I Control 2 x A2+F Level II Control

$\bar{x}$ Mean Value — RNG Range of Acceptable Values

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MSL 2021-06-4
AM 2021-06-11

Rev M 2021-06-11
05-02-0023

Trinity Biotech

Certificate of Analysis

Lot Number: 12110 **Manufacture Date:** 2021-05-24 **Shelf-Life/Expiration Date:** 2023-05-31

Product Name: A2+F Control Material Kit

REF 01-04-0043

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: A2+F Control Material is intended for *in vitro* diagnostic use in laboratory quality control program for the quantitation of HbA2 and HbF.

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

***Ultra2* Resolution™ (Column REF 01-05-0015)**			**Quick Scan Assay**			**High Resolution Assay**		
Lot #	Control		Mean	Low Range	High Range	Mean	Low Range	High Range
12111	Control I	%F	1.7	0.7	2.7	2.0	1.0	3.0
		%A2	2.0	1.0	3.0	2.6	1.6	3.6
12112	Control II	%F	7.7	6.2	9.2	7.8	6.2	9.4
		%A2	5.5	4.4	6.6	5.9	4.7	7.1
		%S	31.5	25.2	37.8	30.9	24.7	37.1

***Ultra2* GeneSys™ (Column REF 01-05-0017)**			**High Resolution Assay**		
Lot #	Control		Mean	Low Range	High Range
12111	Control I	%F	1.9	0.9	2.9
		%A2	2.6	1.6	3.6
12112	Control II	%F	7.3	5.8	8.8
		%A2	6.0	4.8	7.2

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: Melanie Rankin Date: 2021-06-11

MSL 2021-06-11
AN 2021-0611