

A2+F Control Material

REF 01-04-0043

2 Vials A2+F Level I Control
2 Vials A2+F Level II Control

Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych języków

Para outras línguas
Για τις άλλεςλώσσες
För andra språk
For andre språk



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INTENDED USE

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

SUMMARY AND EXPLANATION OF 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

- Lyophilized:** Lyophilized vials stored ≤ 8°C are stable until the expiration date indicated on the label.
- Reconstituted:** Once reconstituted, the Control material is stable ≤ 8°C for 21 days. Aliquots may be stored at -20°C or -70°C for up to 3 weeks in tightly closed containers.
- Diluted:** After final dilution, each control sample is stable for 24 hours at room temperature or refrigerated.

DO NOT USE after the expiration date.

PRECAUTIONS

CAUTION

For *In Vitro* Diagnostic Use ONLY

SAFETY GLASSES, GLOVES AND LAB COAT ARE RECOMMENDED WHEN USING THE TRINITY A2+F CONTROL MATERIAL.

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.

DO NOT USE: If diluted sample turns dark brown.

PREPARATION PROCEDURE

RECONSTITUTION

- Remove the seal and stopper from the vial.
- Add 300µL of 2 Diluent (Ref 01-03-0013, 01-03-0056, or 01-03-0059) to the vial.
- 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 2 Diluent. Mix well.

System	Dilution Ratio	234 Vial µL Control:µL Diluent	Shell Vial or Crimp Top Vial µL Control:µL Diluent
CLC385w/234	1:120	4:476	
CLC385w/215	1:120		15:1785
ultra ² w/215	1:120		15:1785

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 Resolution software or the High Resolution Assay of the GeneSys software, the results should be within the limits indicated below for the CLC385 or *ultra²* instruments:

Kit # XXXX Exp. Date YYYY-MM

Resolution or GeneSys software

	Mean %F	Range %F	Mean %A2	Range %A2	Mean %S	Range %S
Level I Lot XXXX	xx	xx	xx	xx		
Level II Lot XXXX	xx	xx	xx	xx	xx	xx

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

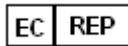
KIT	Item	A2+F Control Material
Catalog No.	Item	Quantity
01-04-0043	A2+F Control Material	2 Vials Level I Control 2 Vials Level II Control




Manufactured




Consult accompanying documents




Authorized Representative




Product Number




Lot




Range




Store at 2-8°C




For *In Vitro* Diagnostic use




Caution, consult accompanying documents



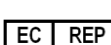
Hazard



Use by



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