

Defects in genes, which are responsible for the synthesis of the hemoglobin molecule, result in a group of hereditary diseases termed as "hemoglobinopathies". Depending on the molecular defect, hemoglobinopathies may be classified in "structural hemoglobin variants" and in "thalassemias". This test kit allows for a reliable separation and identification of the common and clinically significant hemoglobin variants. For β -thalassemia screening the kit ensures an exact quantification of HbF and HbA2. A ready-to-use test solution (containing: HbA1c, HbF, HbA0, HbE, HbA2, HbD, HbS, HbC), a hemolysate calibrator (containing: HbF, HbA2) as well as hemolysate controls in two levels of concentration are available for quality assurance.

Diabetes, Hemoglobin Testing

Hemoglobin Variants and β -Thalassemia Screening in Whole Blood

Test Data

Intraassay precision: 1.0 - 3.3 % (HbF)
0.6 - 3.6 % (HbA2)
Interassay precision: 2.1 - 2.8 % (HbF)
0.7 - 2.4 (HbA2)

Dependence on total hemoglobin:

The HbF and HbA2 values are independent on the amount of total hemoglobin in a range from 6 - 24 g/dl total hemoglobin.

HPLC Parameters

Pump: binary gradient pump
Flow rate: 1.2 ml/min
Injection volume: 20 μ l
Injection interval: 8 min
UV/VIS-Detector: 415 nm
HPLC-Thermostat: 23 $^{\circ}$ C

Sample Preparation

Hemolysis:

5 μ l venous blood	1 ml Hemolysis Reagent H
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HPLC Analysis:

↓ incubate (10 min, ambient temp.)

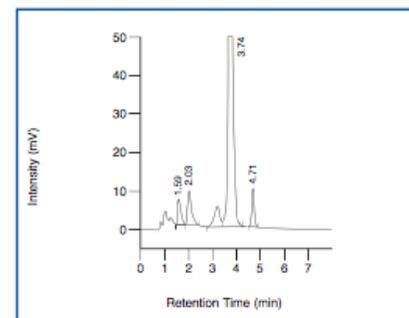
Inject 20 μ l

→ Reliable separation and quantification of HbA2 and HbF

→ Safe identification of HbS, HbC, HbE and HbD

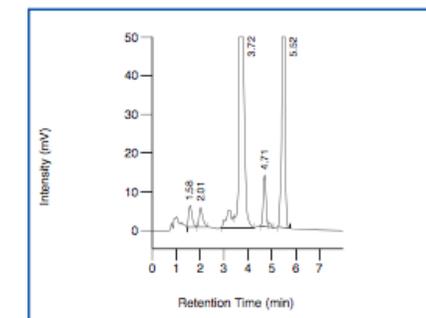
→ Test solution, calibrator and control materials available

ClinCal[®] Hemolysate Calibrator (HbF/A2)



HbA1c: 1.59 min, HbF: 2.03 min, HbA0: 3.74 min,
HbA2: 4.71 min

ClinCheck[®] Hemolysate Control (HbF/A2/S), Level I



HbA1c: 1.58 min, HbF: 2.01 min, HbA0: 3.72 min,
HbA2: 4.71, HbS: 5.52 min

Ordering Information

Order No.	Description	Quantity
13100	ClinRep [®] Complete Kit for Hemoglobin Variants and β -Thalassemia Screening in Whole Blood for 500 assays	1 pce.
Components of the Complete Kit (order no. 13100):		
13101	ClinRep [®] Reagent Kit	1 pce.
13113	Hemolysate Calibrator HbF/A2, ready for use	5 x 3 ml
13130	Analytical Column with test chromatogram	1 pce.
	Manual	1 pce.
	Quick Reference	1 pce.
Components of the Reagent Kit (order no. 13101):		
13107	Buffer 1	2500 ml
13108	Buffer 2	2500 ml
13109	Washing Solution W	2000 ml
13121	Hemolysis Reagent H	500 ml
Optional Components:		
13114	Test Solution (HbA1c/F/A/E/A2/D/S/C), ready for use	5 x 3 ml
Accessories:		
11024	Sample vials 1.5 ml without cap	1000 pcs.
FK5810	PEEK tubing (connection of prefilter and column)	1 pce.
FK5820	Stainless steel prefilter holder	1 pce.
FK5821	Replacement filter for stainless steel prefilter holder	10 pcs.
ClinCheck[®] Controls:		
13182	Hemolysate Control HbF/A2, Level I, II, ready for use	2 x 5 x 3 ml
13183	Hemolysate Control HbF/A2/S, Level I, ready for use	5 x 3 ml