blood

Hemoglobin S Screening Using the « Sickle Scan » – Biomedomics System. the Necker-Enfants Malades Hospital Experience

Louis MINE, Thao Nguyen-Khoa, Birch Allaf, Jean-Antoine Ribeil, Christelle Remus, Valérie Gauthereau, Sarah Enouz, Jason S. KIM, Xiaoxi Yang, Eliane Gluckman, Arnold Munnich, Marina Cavazzana, and Robert Girot

Blood 2016 128:1308;

Abstract

Context: The principle of Sickle Scan (Biomedomics, Inc.) is a rapid, point-of-care qualitative lateral flow immuno-assay kit for the identification of sickle cell conditions of Hb A, S and C. Sickle Scan was specifically developed to allow for the identification of sickle cell trait Hb AS, heterozygotes AC, and Hb SS, Hb SC and Sβ° patients. Other sickle cell conditions as SD, SE, SO-Arab, S Lepore,… cannot be identified using Sickle Scan system. The test must be done using venous blood or capillary blood (fresh or dried blood spots).

Patients and methods: Two hundred and fifty patient samples (143 adults and 107 newborns) were analyzed. All tests were performed according the manufacturer's recommendations in one laboratory by 2 observers. The reference tests used for comparison were HPLC (NBS Variant – Bio-Rad) and capillary electrophoresis (Capillarys 3 – Sebia).

Results:

Comments: In adult patients, the 2 observers concordantly detected the presence of Hb A, Hb S and Hb C. There were 4 differences of interpretation between them (no Hb A in a AS patient and no Hb A in 3 SS transfused patients). The percentage of Hb A in these 3 last patients was respectively 13.6%, 17.7% and 18%. There was no false positivity neither in the patient heterozygous AE nor in the patient SD. No false negativity occurred for Hb S and C. In newborns, the accuracy of the test was excellent for the identification of the phenotypes FA, FAS, FAC, FS (SS / Sβ°). The lowest detected values of Hb S and Hb C in FAS and FAC newborns were respectively 2.4 and 3.4 %. We observed an inconstant cross-reactivity of the antibody anti Hb S with the hemoglobins E and D, in respectively 3/25 FAE phenotype and 6/26 in the FAD phenotype. There was no cross reaction with hemoglobin Bart's and O-Arab.

In FAS newborns the mean and extreme values of the percentage of Hb A were m=8.2 (2.6-15.5) and no difficulties occurred for the identification of these low percentages of Hb A. This observation is different from those made in adult patients for which one observer did not find Hb A in transfused patients with highest values of Hb A comprised between 13.6 and 18.

Conclusions: In this series of adult and newborn patients, the Sickle Scan appeared as an accurate method for the identification of AS, AC, SS/Sβ° and SC phenotypes. False positive tests were observed in some patients with hemoglobin E or D but no false negative results were found as regards the identification of Hb S and Hb C.

ADULT PATIENTS			
Phenotype	Reference test	Sickle Scan®	Divergence
AA	73	73	0
AS	23	22	1 S only (one observer)
AC	4	4	0
SC	9	9	0
SS/Sβ0	13	13	0
SS + transfu-sion	18	15	3 S only (one observer)
AE	1	1 A only	0
SD + transfu-sion	2	2 A+S	0
Total	143		4

NEWBORNS			
Phenotype	Reference test	Sickle Scan®	Divergence
FA	1	1	0
FAS	23	23	0
FAC	7	7	0
FS (SS/Sβ0)	14	14	0
FSC	5	5	0
FAE	25	22	3 A + S weak
FAD	26	20	6 A + S weak
FC	3	3	0
FA Bart's	2	2	0
FA O/Arab	1	1	0
Total	107		9