

Colour Scale For HaemoglobinTM

Catalouge



Colour Scale For Haemoglobin™



***“Colour Scale For Haemoglobin”
is an ingenious & validated strip method to know your
Haemoglobin on the spot.***

Color Scale for Haemoglobin

Is the simple, reliable and inexpensive answer to Screening Anemia.

How to screen anemia in the absence of laboratory - based haemoglobinometry?

How does the Haemoglobin Colour Scale work?

Anemia: Information, Detection, Management.....

Anemia is the most serious complication of iron deficiency and a significant cause of death. More than half of the pregnant women in developing countries suffer from anemia. The accurate estimation of haemoglobin levels is an essential prerequisite in a variety of other health issues, such as trauma care, selection of blood donors, epidemiological studies, and general primary health care.

The measurement of haemoglobin has long been recognized as fundamental in routine health checks, for the diagnosis and treatment of disease and, given the global incidence of anemia, in public health care.

The measurement of haemoglobin in blood as an indicator of anemia has traditionally relied on the services of a well-equipped clinical laboratory.

Simple techniques do of course exist, but even these are relatively expensive and require commercial reagents, a good degree of technical skill and are not readily available in peripheral health clinics or at point of care for clinicians and midwives.

In primary health care centre's, where laboratory facilities are not available, anemia is usually diagnosed from clinical signs (pallor of the conjunctiva, tongue, palms and nail beds, using anemia recognition cards if available), although accurate interpretation of these signs depends a great deal on effective training. However, in rural areas where anemia is common and where appropriate prevention and treatment strategies may be most beneficial, an alternative method is needed to screen for anemia easy and economically.

Colour Scale for Haemoglobin is a simple and effective *medical device* for the accurate estimation of haemoglobin levels in blood.

It comprises a small card with six shades of red that represent haemoglobin levels at 4, 6, 8, 10, 12 & 14 g/dl respectively.

The device is simple to use:

? place a drop of blood on the test strip provided

? wait about 30 seconds

? match immediately the colour of the blood spot against one of the hues on the scale.

This will indicate whether the patient is anemic and, if so, the severity of anemia in clinical terms. It will not identify minor changes in haemoglobin during treatment, but rather assist in the management of any patient with suspected anemia, e.g. to decide whether a patient may require a blood transfusion a blood count, be referred for laboratory tests or to a hospital or clinic for treatment.

14 g/dl	healthy
12 g/dl or more	not anemic
8-11 g/dl:	mild to moderate anemia
6-7 g/dl:	marked anemia
4-5 g/dl:	severe anemia
Less than 4 g/dl:	critical

Training

In a validation study, most results were accurate to within 1–1.5 g/dl. Further analysis showed that the discrepancies in the results of the original study were largely due to a lack of training and thus incorrect technique, e.g. not waiting for 30 seconds, reading in a shadow or not having an adequate sized drop of blood.

As a result, it was shown that a half-hour training session was sufficient for health workers to estimate haemoglobin to within 1g/dl, and **assess levels of anemia much more effectively than by traditional clinical diagnosis.**

Validation in the field

For severe anemia, the Scale shows a sensitivity of 95% and a specificity of 99.6%. To distinguish normal from mild anemia, the sensitivity and specificity are 98% and 86% respectively, results that are well above the reliability of any clinical measurement. Using a photometer (STAT-SITE M ®-USA) as a reference, the Scale was compared with the copper sulphate specific gravity method that is traditionally used to screen blood donors for anemia. The scale was accurate to 98% in distinguishing among volunteer blood donors & school Children those with normal Hb from those rejected because of anemia.

The Scale was more reliable than copper sulphate, the tests giving 2.4% and 5.4% false readings respectively. Moreover the copper sulphate presents a potential environmental hazard in the disposal of used solutions.

The idea is not new. Tallqvist, among others, tried in vain as long ago as 1900 to substantiate the theory that the colour of a drop of blood could reliably indicate anemia. The colour printing technology and test-strip paper available at that time were such that the results were inaccurate and the concept shelved.

It has taken modern technology to perfect the material on which blood can be absorbed, and computerized spectrometric analysis to identify colours that can accurately match shades of Haemoglobin at different concentrations.

Color Scale FOR Haemoglobin is now available in INDIA as a simple and effective *medical device* for the accurate estimation of hemoglobin levels in blood.

Validation: “Colour Scale for Haemoglobin” is fully validated in August 2009 by India’s largest & internationally renowned laboratory RELIGARE Laboratories Ltd. [Formally known as Ranbaxy Lab.Ltd.] A brief extract of the report is as under:

Conclusion

Colour Scale test kit for Haemoglobin was validated, The rapid method showed good correlation for normal values, also reprobucibility was, acceptable. Method comparison with automated blood cell counter (LH-750 Beckman Coulter) was found to be excellent. Basing on the above data, it is recommended to use Colour Scale test kit for rapid estimation of Haemoglobin levels.

RELIGARE Laboratories Ltd



Evaluation Report

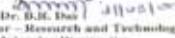
Name of the Test Evaluated	Colour Scale For Haemoglobin
Name and Address of Supplier	Allied Healthcare Pvt Ltd 111-A, Khandri Katti (Behind Noida Bldg), Aurang, New Delhi 110014
Evaluated During	August 2009
Evaluation Protocol	<ul style="list-style-type: none"> ➤ Reference Range of the test using normal population (n=70) ➤ Precision <ul style="list-style-type: none"> ▪ Intra-Assay Variation (Two specimens assayed 20 times in same run) ▪ Inter-Assay Variation (One Specimen assayed 3 times in 3 runs) ➤ Method Correlation with automated Cell Counter (I.H-750) using 20 specimens
Results	<p>Obtained Reference Range - (11.79 -14.8) g/dl, all the 20 normals showed Hemoglobin values equal to or greater than 12.0 g/dl</p> <p>Precision - Acceptable (% C.V. = 10.4%) Intra Assay = 6.8-7.5% Inter Assay = 8.2%</p> <p>Method Correlation - Regression analysis (r=0.97) indicates excellent correlation of results with Automated Cell Counter (I.H-750)</p>
Conclusion	Performance of Colour Scale test kit for Hemoglobin was found to be acceptable

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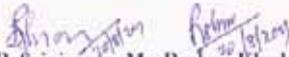
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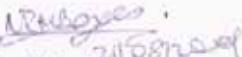
Conclusion:

Colour Scale test kit for Haemoglobin was validated. The rapid method showed good correlation for normal values, also reproducibility was acceptable. Method comparison with automated blood cell counter (I.H-750 Beckman Coulter) was found to be excellent. Basing on the above data, it is recommended to use Colour Scale test kit for rapid estimation of Haemoglobin levels.

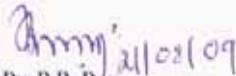
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CCPCPL



Registration Certificate

Issued to
**ALLIED HEALTH SCIENCES
PVT. LTD.**

Carried out at following site:
101 - A, KUNDAN KUTIR, ASHRAM,
NEW DELHI - 110 014 (INDIA)

for their
**QUALITY MANAGEMENT SYSTEM
ISO 9001:2008**

Scope of Activities covered by this Registration:
DEVELOPMENT & MARKETING OF COLOUR
SCALE FOR HAEMOGLOBIN TEST KITS,
IN - VITRO DIAGNOSTIC ANALYZERS / REAGENTS &
RESEARCH INSTRUMENTS WITH CONSUMABLES &
TECHNICAL SUPPORT FOR PRODUCTS

REGISTRATION NO. : CCPL/GMS/D1350

ISSUED ON : 02/04/2010

VALIDITY DATE : 01/04/2013

SUBJECT TO SUCCESSFUL SURVEILLANCE ASSESSMENT

THIS IS A SINGLE-SITE CERTIFICATION

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To whom It may concern

M/S Allied Health Sciences Pvt. Ltd. New Delhi has participated in Anemia Control Programme organized under my supervision for the school children studying in MCD Schools.

In MCD Primary School Nand Nagari M/S Allied Health Sciences Pvt. Ltd. organized the Hb testing by using two methods i.e. Hemocue Machine and Colour Scale for Hemoglobin strip test method (devised by the firm).

The test was conducted on more than 500 children and it was observed that there is only 1% difference in results in both the methods.

Colour scale method can be a good system for mass screening in peripheral areas as it is quite reliable and quick.

V.K. Monga
(Dr. V.K.Monga)



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