User instructions • Erythrocytes kit • ERY 142

Article No. ERY 142
Name Erythrocytes Kit
Contents 40 round cuvettes
Ready-to-use reagent (2.5 mL)

Short description
Kit for the photometric determination of Erythrocytes in the blood using photometric turbidity measurements in round cuvettes

Manual, non-automated method for the quantitative determination of Erythrocytes concentration using a Diaglobal photometer

In-vitro diagnostic device for single-use

Sample material
Capillary blood or venous blood

Intended use
Detection of anemia or polyglobulia as well as clarification in cases of suspected internal bleeding, vitamin deficiency, and oxygen deficiency
Haemolytic anemias are characterised by reduced Ery values in the blood that are outside the reference range and are found, among other things, in chronic blood loss, infections, rheumatic diseases, and a number of tumor diseases.

Suitable for laboratory and near-patient testing

Not intended for self-testing

User
Suitable for near-patient diagnostics

Ambulances, hospital emergency rooms, registered doctors

Gynaecologists who carry out Erythrocytes measurements to detect blood loss and vitamin deficiencies in their own practices as part of postnatal care

The measurement takes place in the presence of the patient so that a treatment plan can be initiated immediately.

Measuring principle
By placing the blood sample in Gowers' solution the Erythrocytes are converted into spherical form and photometrically recorded by means of turbidity measurements.

Reagent
Ready-to-use aqueous reagent (2.5 mL)
Concentration of the active ingredients:
Gowers' solution, consisting of:
Sodium sulfate 194 mmol/L
Acetic acid 2.8 mol/L
pH = 2.5

Storage and Shelf Life
Store at 15 to 25°C

Best before the expiry date stated on the packaging

Analytical measuring range
1.0 - 10 Mio/µL

Measuring devices and measuring conditions

Measuring device	Diaglobal photometer
Measuring wavelength	546 nm
Measurement against	Reagent blank value
Measuring temperature	Room temperature

Calibrators
Diaglobal photometers are factory calibrated; calibration by the user is not possible.

Collection and treatment of the sample
The extraction is carried out with a ring marked capillary (10 µL)

Do not use end-to-end capillaries

Use capillary blood immediately for determination
Avoid pressing too hard with the fingertip, otherwise the blood to be extracted will be diluted by tissue fluid.

Whole blood, and venous blood (EDTA or heparin as anticoagulant) can be stored at 15°C to 25 °C, for up to 24 hours.

Sample preparation is not required.

Instructions

Pipette ERY 142 into round cuvette	
	Analysis
Blood	10 µL
Eject blood with a micropipette, rinse the capillary by pulling it up and ejecting the sample several times	
Close round cuvette, mix well, measure after at least 3 min and within 20 min	
Select test <ERY>	
Set the zero point with the unprocessed round cuvette, remove the round cuvette after the signal tone	
Place the round cuvette with the blood sample in the photometer	
Read the measured value	

Calculation
The Erythrocytes concentration is calculated using the equation stored in the unit, the result of the measurement is shown directly on the display.

$c\ (Mio/\mu L) = A \times E^2 + B \times E + C$

E = Absorbance (546 nm)

Quality Control
Erythrocytes control material *ERY QS* from Diaglobal GmbH

Control blood *Para 12 Extend (low, normal, high*) from the Streck company

Participation in surveys according to the guideline of the German Medical Association for quality assurance of medical laboratory examinations does not apply, since the determination is carried out as an individual test in the presence of the patient.
Only an internal quality control is required.

Features of analysis performance

Correctness
The correctness of the analytical results is proven by surveys by the RfB (Reference Institute for Bioanalytics) and control blood measurements.

Method comparison
A comparison of the Diaglobal test ERY 142 (y) with another test based on the reference method (x), carried out with human blood, showed good conformity.
Regression analysis
Passing-Bablok y = 0.969x - 0.002
Lin. Regression y = 0.970x - 0.018
r = 0,999
n = 80
Concentration range: 2.04 - 6.14 Mio/µL

Precision
The reproducibility was checked with control blood.
Typical VK values are listed in the table below.

In the series N = 20	Average [Mio/µL]	Standard deviation [Mio/µL]	VK [%]
Sample 1	1.88	0.03	1.7
Sample 2	4.11	0.05	1.3
Sample 3	5.50	0.05	0.9
From day to day N = 20	Average [Mio/µL]	Standard deviation [Mio/µL]	VK [%]
Sample 1	1.90	0.04	1.9
Sample 2	4.14	0.07	1.6
Sample 3	5.54	0.06	1.1

Linearity
The linearity was examined with human and control samples by variation of the sample volume and is given up to a concentration of 10.3 Mio/µL.
The Cusum Test does not show a deviation from the linearity.

Analytical sensitivity
Lower detection limit: 0.17 Mio/µL

Analytical specificity
The determination of the Erythrocytes count with the help of the turbidity measurement only leads to exact values if the Erythrocytes contained in the blood sample have a normal size (MCV 93 ± 10).
In the presence of pronounced micro- or macrocythaemia, under- or over results are to be expected. In these cases, microscopic counting or determination using cell counters is preferable.
Interferences caused by lipaemia or high leukocyte counts, on the other hand, are of secondary importance and do not usually cause any error in the measurement result.

Reference values

	Mio/µL
Women	4.1 - 5.1
Men	4.5 - 5.9
Children from 5 years	3.7 - 5.8

Cautions
Keep away from children

Safety information
Classification of the reagent ERY 142 according to EC Regulation 1272/2008 (CLP)
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes severe eye irritation

A safety data sheet is available on request.

The reagent does not contain any CMR or endocrine disrupting substances or substances that could cause sensitisation or allergic reactions in the patient or user.

All serious incidents related to the product must be reported to the manufacturer and the relevant authority.

Disposal considerations
Do not allow reagent to enter surface water or any sewage system.
Cuvettes with reagent are classified as hazardous waste. Dispose of it in accordance with local regulations.
Uncontaminated and completely emptied packaging can be recycled.

Other materials

Item No.	Description
LH 004	Capillaries 10 µL, ring marked
LH 007	Micropipetter
LH 001	Blood lancets
LH 006	Cuvette stand
LH 011	Alcohol pads for disinfection
LH 009	Cellulose swab

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