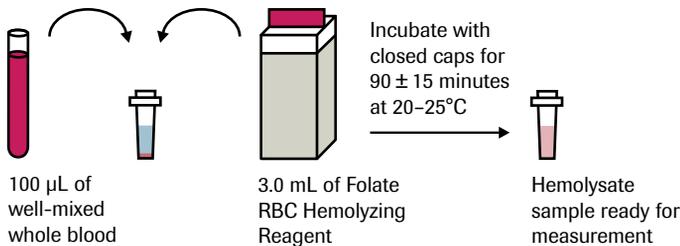


Elecsys® Folate RBC

Electrochemiluminescence immunoassay (ECLIA) for the in vitro quantitative determination of folate in erythrocytes (red blood cells, RBC)

Indication

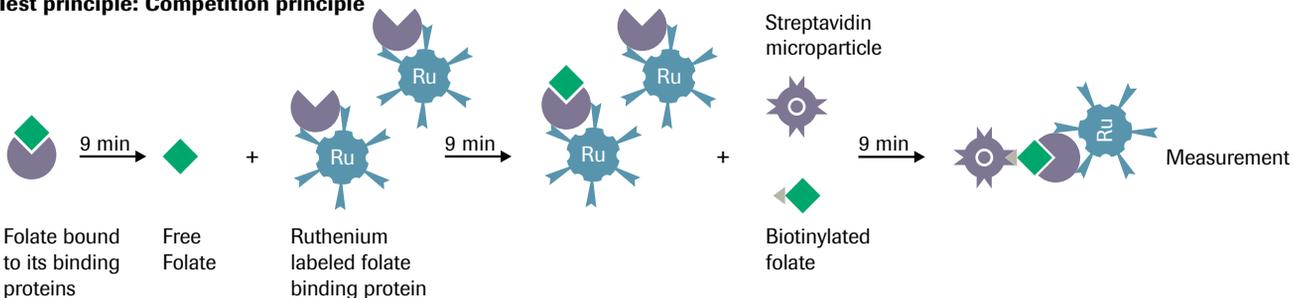
Folate is essential for normal metabolism, DNA synthesis and red blood cell regeneration. Untreated deficiencies may lead to megaloblastic anemia. For diagnosis of folate deficiency, it is recommended to perform determinations not only in serum but also in erythrocytes.⁵ More than 95% of folate occurs in the red blood cells. The folate concentration in erythrocytes more truly reflects the overall folate concentration in the tissue while the serum or plasma level reflects the preceding uptake of folates from the food and fluctuates significantly with the diet. Following dietary deprivation of folate, serum levels decline within 3 weeks, but RBC folate levels remain the same for 3–4 months.^{2, 3, 4} Therefore, the Elecsys Folate RBC assay is used as an aid in the diagnosis of folate deficiency in erythrocytes.



Preparation of the hemolysate sample

Whole blood treated with anticoagulants (heparin or EDTA) is mixed with ascorbic acid solution and incubated for approximately 90 minutes at 20–25°C. Lysis of the erythrocytes takes place, with liberation and stabilization of the intracellular folate. The resulting hemolysate sample is then used for subsequent measurement.

Test principle: Competition principle



1st incubation (9 minutes)

By incubating 25 µL of sample with the folate pretreatment reagents 1 and 2, bound folate is released from endogenous folate binding proteins.



Life needs answers

2nd incubation (9 minutes)

By incubating the pretreated sample with the ruthenium labeled folate binding protein, a folate complex is formed, the amount of which is dependent upon the analyte concentration in the sample.

3rd incubation (9 minutes)

After addition of streptavidin-coated microparticles and folate labeled with biotin, the unbound sites of the ruthenium labeled folate binding protein become occupied, with formation of a ruthenium labeled folate binding protein-folate biotin complex. The entire complex becomes bound to the solid phase via interaction of biotin and streptavidin.

Measurement

The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.

Elecsys® technology

ECL (ElectroChemiluminescence) is Roche's technology for immunoassay detection. Based on this technology and combined with well-designed, specific and sensitive immunoassays, Elecsys delivers reliable results. The development of ECL immunoassays is based on the use of a ruthenium-complex and tripropylamine (TPA). The chemiluminescence reaction for the detection of the reaction complex is initiated by applying a voltage to the sample solution resulting in a precisely controlled reaction. ECL technology can accommodate many immunoassay principles while providing superior performance.

Elecsys® Folate RBC test characteristics

Testing time	27 minutes
Test principle	Competitive assay
Calibration	2 point
Traceability	Standardized against the Folate III assay / RBC application
Sample material	Hemolysate prepared from whole blood treated with anticoagulants (Na-heparin or K3-EDTA).
Sample volume	100µL whole blood
LoB, LoD, LoQ	20.0 ng/mL, 46.5 ng/mL, 120 ng/mL
Measuring range	120 – 620 ng/mL or 272 – 1'407 nmol/L
Intermediate imprecision	cobas e 411 analyzer: 4.7 – 14.2 % cobas e 601/e 602 modules: 3.4 – 10.4 % Lowest conc. measured: 61.0 ng/mL
Expected values	Whole blood folate (from hemolysate samples) Europe: 212 – 534 ng/mL, Australia: 241-584 ng/mL RBC folate (folate in erythrocyte fraction) Europe: 523 – 1'257 ng/mL, Australia: 629 – 1'453 ng/mL, (2.5 th – 97.5 th percentile)

* LoB = Limit of Blank; LoD = Limit of Detection; LoQ = Limit of Quantitation (20 % total error)

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Order information

Elecsys Folate RBC	100 tests	05944295 190
Folate RBC CalSet	2 × 1 mL each of CalSet Calibrator 1 and 2	05944309 190
Folate RBC Hemolyzing Reagent kit	for 4 × 200 mL	05944317 190
Bio-Rad Lyphocheck Whole Blood Control	6 × 2 mL for each Level 1, 2 and 3	Order from Bio-Rad directly (order number 561, 562, 563 or 560x)