

# **Certification Report**

**AOAC Research Institute**

**Performance *Tested Method***  
**080201**

**Folic Acid Kit**

*(Catalog number– BR-1003-39)*

manufactured by

**Biacore AB**  
Rapsgatan 7  
**S-754 50 Uppsala**  
**Sweden**



**August 2, 2002**

The Biacore Folic Acid Kit has been validated and certified as a *Performance Tested Method* by the AOAC Research Institute as an accurate and reliable method for the measurement of folate in selected foods including cereals, milk powder, pre-mixes, milk based infant gruel and soya-based infant gruels.

The Biacore Folic Acid assay utilizes the principle of Surface Plasmon Resonance (SPR) and is based on the principle of inhibition. A derivative of the analyte (folic acid) is covalently bound to the sensor surface. A sample or standard that contains the analyte is mixed with an excess of a specific antibody. Free antibody that has not bound to analyte can bind to the surface and in this way give rise to a response.

The kit includes a sensor chip with a gold layer that creates the physical conditions required for SPR. SPR detects changes in mass in the aqueous layer close to the sensor chip surface by measuring changes in refractive index. When molecules in the test solution bind to a target molecule at the sensor chip surface the refractive index increases, when they dissociate the refractive index falls. This simple principle forms the basis of the sensorgram – a continuous, real-time monitoring of the association and dissociation of the interacting molecules.

The binding to the surface takes place under conditions that are limited by mass transport, which means that the degree of response is directly proportional to the time of contact of the sample on the surface, that is, the injection volume. The response is measured as the difference in absolute response obtained immediately before and immediately after the injection of the sample.

## 1.0 SCOPE OF METHOD

- 1.1 Target Analyte - Folic acid.
- 1.2 Matrices - Cereals, milk powder, pre-mixes, milk based infant gruel and soya-based infant gruels.
- 1.3 Summary of validated performance claims

Accuracy, compared with microbiological analysis	97-100%
Parallelism, compared with different folic acid solutions	93-104%
Repeatability	3-5%
Reproducibility	5-10%
Precision within one run	1%
Precision between runs	2%
Precision between kits, same calibration solutions	2%
Precision between kits, different calibration solutions	3%
Recovery	87-96%
Detection limit	<1 ng/ml
Quantifiable region	2.0-70 ng/ml
Dilution of sample extracts	2-5%cv
Different amounts of sample	2-14%cv
Variation of the calibration curve	84% of runs under 5%cv in Cal 2-5

## 2.0 ORDERING INFORMATION

2.1 Name: Folic acid kit

2.2 Code nr: BR-1003-39

2.3 Ordering Information:

### USA Headquarters

Biacore Inc.  
Suite 100  
200 Centennial Avenue  
Piscataway NJ 08854  
[www.biacore.com](http://www.biacore.com)  
Thomas Grace  
National Account Manager  
Food Analysis  
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Mobile: 732-809-1545  
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SE Uppsala-754 50  
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Fax: +46 18 150111  
Internet: [www.biacore.com](http://www.biacore.com)

## 3.0 TEST KIT REAGENTS

3.1 Folic Acid Kit Antibody Solution

3.2 Folic acid for calibration solutions is supplied as a stock solution (concentration 100 µg/ml).

3.3 Regeneration solution: Sodium hydroxide and polysorbate

- 3.4 Conditioning solution: Sodium hydroxide and trisodium EDTA
- 3.5 Running buffer: HBS-EP

#### 4.0 ADDITIONAL SUPPLIES AND REAGENTS NEEDED

- 4.1 Variable micropipette, 200 –1000  $\mu$ l
- 4.2 2 volumetric flasks, 100 ml
- 4.3 Calibrated balance (range at least 20 g, accuracy  $\pm$ 0.01 g)
- 4.4 Filter units, 0.22  $\mu$ m (Millex GS recommended)
- 4.5 Disposable syringes, 1 or 5 ml
- 4.6 Deionized water, resistivity  $\geq$  18 M  $\Omega$  cm ( e.g. Milli-Q)
- 4.7 Ultrasonic bath
- 4.8 Centrifuge
- 4.9 Autoclave

#### 5.0 APPARATUS

- 5.1 Biacore Q – Biacore AB
- 5.2 Biacore Q consist of a processing unit with liquid handling and optical systems and a PC running Biacore Q Control Software.
- 5.3 Sensor chips and other consumables are available from Biacore AB.
- 5.4 Biacore Q can also run under the control of BiacoreQuant™ Software for routine vitamin concentration measurements with ready-to-use kits available from Biacore AB.
- 5.5 Ultrasonic bath: Branson 5210
- 5.6 Autoclave

#### 6.0 STANDARD REFERENCE MATERIALS

- 6.1 AACC (American Association of Cereal Chemists) reference sample.
- 6.2 NIST 1846
- 6.3 IRMM 421