



## 产品检验报告单

产品名称：叶酸检测国标即用型套装 批号：GF012102  
产品货号：GVT1001 报告日期：2021.3.25  
产品有效期：03-2022 包装：无菌密封  
检验依据：GB 5009.211-2014

### 理化特性

产品组分	批号	有效期	理化性状
叶酸标准品（冻干）	GF012102	03-2022	底部有一层无色冻干物
叶酸检测菌球（冻干）			白色冻干菌球
叶酸测定培养基添加剂（冻干）			底部有一层白色冻干结晶体
叶酸测定培养基基础			澄清透明的淡黄色液体

说明：（1）叶酸测定培养基基础冷藏放置时间久了会出现少量白色结晶物，属于个别成分过饱和析出，为正常现象，在使用时不吸取即可，不影响实验结果。

（2）叶酸测定培养基基础在加入添加剂后颜色由淡黄色变成褐色，属于正常现象，恢复室温后颜色会逐渐变回淡黄色。

### 微生物学检验

标准曲线	叶酸标准曲线	
标准质控样	评定标准	检测结果
	标准质控样品 1: 119.41~174.69 μg/100g	145μg/100g
	标准质控样品 2: 223.9μg/100g±8.6μg/100g	216μg/100g

备注：1、培养条件：36℃/46h。

2、吸光度值为 550nm 条件下酶标仪测定 300μL 培养液结果。

结论

检验：

刘蕾

复核：

谷丛佳

审核：

刘沛

产品检验专用章



## 关于国标套装中叶酸标准品的来源说明

【产品名称】叶酸标准品

【产品批号】GF012102

【标准品来源】标准品购买于 DR.Ehrenstorfer，标准品证书如下：

Certificate of Analysis		EHC   EHRENSTORFER	
<b>ISO Guide 34 Reference Material</b>			
<b>Product Identification</b>		<b>Lot Number:</b>	G168864
Article Code: DRE-C13888000		<b>Expiry Date:</b>	02.05.2021
Article Name: Folic acid		<b>Storage Temperature:</b>	20°C ± 4°C
Formula: C <sub>19</sub> H <sub>19</sub> N <sub>7</sub> O <sub>6</sub>			
Mol. Weight: 441.40			
CAS No.: 59-30-3			
Storage and handling: The RM should be stored in the original sealed bottle at the temperature given above. After use the bottle should be tightly closed and protected from moisture.			
Purity: 91.34% (g/g)			
Expanded Uncertainty U <sub>95</sub> : 0.32% (g/g)			
The uncertainty of this standard is calculated in accordance with the ISO Guide 34 and EURACHEM/CITAC Guide: Quantifying Uncertainty in Analytical Measurement, Second Edition. The expanded uncertainty is U <sub>95</sub> (g/g) = u(g/g) × k, where k is the coverage factor at the 95% confidence level (k=2). Uncertainty u(g/g) is based on the combination of the uncertainties associated with each individual operation involved in the analysis of the product: u(g/g) = √[u <sub>char</sub> <sup>2</sup> + u <sub>lab</sub> <sup>2</sup> + u <sub>ref</sub> <sup>2</sup> + u <sub>st</sub> <sup>2</sup> + u <sub>hom</sub> <sup>2</sup> + u <sub>stab</sub> <sup>2</sup> + u <sub>acc</sub> <sup>2</sup> + u <sub>res</sub> <sup>2</sup> ]. u <sub>char</sub> (g/g) is the uncertainty of characteristics, u <sub>lab</sub> (g/g) is the uncertainty of homogeneity test, u <sub>ref</sub> (g/g) is the uncertainty of stability test (long-term), u <sub>st</sub> (g/g) is the uncertainty of stability test (short-term), u <sub>hom</sub> (g/g) and u <sub>stab</sub> (g/g) are not included in the calculation as the stability statements are based on real evidence assessed by simulation. Minimum sample: 1 mg is recommended as the minimal sample amount. If less material is used, it is recommended to increase the certified uncertainty by a factor of four for half sample and a factor of four for a quarter of sample. Standard use: Use this RM as calibrant for chromatography or any other analytical technique.			
<b>Analytical Data</b>			
Traceability of chromatography: To the International System of Units (SI).			
Instrument: HPLC/DAD		Method Details	
Detection: DAD		Event A: H2O+0.1M H3PO4 for 1 min	
Column: Nucleosur C18 Pyramid 3 µm 150 × 4 mm		Event B: Acetonitrile 100% for 1 min	
Inj. Vol.: 10 µl		Event A + B: 8.23 min	
Flow: 1.0 ml/min			
Ret. Time: 5.87 min			
<b>Comment</b>			
Traceability: The balances used are calibrated with weights traceable to the national standards (DIN).			
Calibrated class A glassware is used for volumetric measurements.			
Water Content: 8.69% (g/g) by Karl-Fischer-Titration (U <sub>95</sub> ) = 0.27% (g/g).			
Identity: EA, NMR, RT, IR, UV, MS.			
Certificate Revision 1 - 03.05.2018 - M. Beck			
Certified on: 03.05.2018		Authorized copy from Ehrenstorfer 04.04.2018	
Certified by: M. Beck M. Beck			
The LGC Labor GmbH, accredited by DAkkS as indicated by the accreditation number D-9661989-01 & D-9661989-02, has shown competence based on ISO Guide 34:2009 with relevant parts of DIN EN ISO/IEC 17025:2005 for production of certified reference materials in form of organic pure substances and in form of single and multi-component solutions of organic pure substances.			
LGC Labor GmbH - Reg.-Nr./Händler-Strasse 6A - 82169 Augsburg - Germany Phone: +49 821 906080 - Fax: +49 821 906088 - augsburg.inquiry@lgcgroup.com The warranty for this product is limited to the purchasing price of this product.			

【制备方法】购买来的标准品经配制、稀释、标定、定量冻干制得本品。

【性能验证】

经验证其浓度、稳定性，满足《GB 5009.211-2014 食品安全国家标准 食品中叶酸的测定》的要求，通过国内外两个质控样的验证，测定值均在要求范围内。

【废物处理】本标准品不含有害成分并且含量较低，可以当做一般废液直接处理。




## 关于国标套装中叶酸检测菌球的来源说明

【产品名称】叶酸检测菌球

【产品批号】GF012102

【菌株来源】菌株购买于美国模式培养物集存库（ATCC），菌株证书如下：

Microbiology	
Certificate of Analysis: Labeled Microorganism Specification and Performance Upon Release	
<b>Specifications</b> Microorganism Name: Lactobacillus rhamnosus Catalog Number: C235 Lot Number: 233-33** Reference Number: ATCC® 7469™** Purity: Pure Passage from Reference: 3	Expiration Date: 2021/2/28 <b>Release Information:</b> Quality Control Technologist: Carol J Stanoch Release Date: 2019/3/11
<b>Macroscopic Features:</b> Small to medium, circular to irregular, raised, entire edge, white/gray, SBAP Distending, translucent <b>Microscopic Features:</b> Gram positive rods, with rounded to square ends, some forming chains	<b>Performance</b> <b>Medium:</b> SBAP <b>Method:</b> Gram Stain (1)
<b>ID System:</b> MALDI-TOF (1) See attached ID System results document	<b>Other Features/Challenges/Results</b> (1) Catalase (3% Hydrogen Peroxide): negative (1) Vancomycin (30 mcg - Disk Susceptibility): resistant (no zone)
 Amanda Kuperus Quality Control Manager AUTHORIZED SIGNATURE	
<small>*Disclaimer: The last digit(s) of the lot number appearing on the product label and packing slip are merely a packaging event number. The lot number displayed on this certificate is the actual base lot number.</small> <small>Note for Vitek®: Although the Vitek® panel uses many conventional tests, the unique environment of the card, combined with the short incubation period, may produce results that differ from published results obtained by other methods.</small> <small>Refer to the enclosed product insert for instructions, intended use and hazard/safety information.</small> <small>Individual products are traceable to a recognized culture collection.</small>	
 <small>ATCC Licensed Distributor</small>	
<small>(*) The ATCC Licensed Derivative Emblem, the ATCC Licensed Derivative logo mark and the ATCC catalog marks are trademarks of ATCC Microbiology, Inc. It is licensed to use these trademarks and to sell products derived from ATCC.</small> <small>(1) These tests are accredited to ISO/IEC 17025:2005.</small>	
 <small>TESTING CERT #2605-01</small>	

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【性能验证】

经验证其活性、稳定性及对叶酸的敏感性，满足《GB 5009.211-2014 食品安全国家标准 食品中叶酸的测定》的要求，通过国内外两个质控样的验证，测定值均在要求范围内。

【废物处理】一切含菌的试验材料应置于 121℃ 下湿热灭菌 30min 之后丢弃。



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