

## 大安聯合醫事檢驗所公告

公告編碼：448

日期：114年03月11日

公告事項： 1. 檢驗項目17-Hydroxycorticosteroids, 17-OHCS 17氫氧根腎上腺酮，停止服務。  
2. 檢驗項目17-Ketosteroids, 17-KS 17酮類固醇類，停止服務。

1. 檢驗項目17-Hydroxycorticosteroids, 17-OHCS 17氫氧根腎上腺酮，自114年03月15日起停止操作，因國外廠商告知試劑將停止生產，該項目不再提供服務。
2. 檢驗項目17-Ketosteroids, 17-KS 17酮類固醇類，自114年05月31日起停止操作，因國外廠商告知試劑將停止生產，該項目不再提供服務。

請參閱附件

謹此敬告週知修正，通知事項同步公告於本所網頁



陳明輝

大安聯合醫事檢驗所  
負責人 陳明輝 敬上

# Chromatography line

Dear partner,

We are writing to inform you about an important update regarding some of our products. Due to the new In Vitro Diagnostic Medical Device Regulation (IVDR) requirements and the increasing difficulty in sourcing the raw materials required for production, the **chromatography products in our portfolio will be discontinued**.

The IVDR brings significant advancements in safety, quality, and performance standards for in vitro diagnostic devices, which we fully support. Additionally, the availability of necessary raw materials for chromatography kits has significantly decreased, making it increasingly challenging to maintain production.

After a thorough evaluation of these circumstances, we have determined that continuing to offer these products is no longer feasible.

For a detailed list of discontinued products, please refer to the table below.

## REFERENCES TO BE DISCONTINUED

Code	Description
11002	17-KETOSTEROIDS 40 t
11003	VANILMANDELIC ACID 20 t
11006	17-HYDROXYCORTICOSTEROIDS (17-OH) 40 t
11010	5-HYDROXYINDOLEACETIC ACID (5-HIAA) 40 t
11017	5-AMINO ACID(ALA)/PORPH. GEN(PBG)40 TEST
11022	METANEPHRINES 40 t
11077	HEMOGLOBIN A2 20 t

We understand the importance of ensuring you have the products you need during this transition. That's why **we're planning to produce one final lot** of the discontinued items. To tailor production to your specific requirements, please **let us know your**

**needs by February 28th**. Your input will help us provide the right quantities to support you effectively.

We sincerely appreciate your understanding as we navigate these regulatory changes together. Thank you for your continued trust in us to provide reliable analytical solutions for your needs.

If the content of this communication involves registration procedures, please contact our Regulatory Affairs Manager, Laura López ([llopez@biosystems.es](mailto:llopez@biosystems.es)).

For further information, please do not hesitate to contact us.

Best regards,

**Clinical analysis team**

BioSystems  
[www.biosystems.global](http://www.biosystems.global)

