

July 14<sup>th</sup>, 2020

## Urgent Field Safety Notice

**Product code:** K-15S2  
**Product name:** HAT Sero K-SeT  
**Batch number:** 42874D2003

**Reference:** FSN\_NC2170

**Type of action:**

- Advice regarding the use of the device

**Details on affected devices:**

The batch number 42874D2003 of the product *HAT Sero K-SeT* is affected.

**Description of the problem:**

Please be informed that *HAT Sero K-SeT*, *in vitro* rapid detection test of antibodies specific to *Trypanosoma brucei gambiense* in human whole blood, serum or plasma, with catalogue reference K-15S2 and the batch number 42874D2003 has been mislabeled.

The wrong labelling implies that the expiry date on the products, 2022-02-04, is not correct. The real expiry date of the batch, 42874D2003, is **2021-11-23** (YYYY-MM-DD).

**Advise on action to be taken by the user:**

The product *HAT Sero K-SeT* with the batch number, 42874D2003, has to be used before the 2021-11-23 (YYYY-MM-DD) to comply with our stability studies.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

**Contact information:**

This action reflects Coris BioConcept's commitment to high quality standards and ensuring that our products fully meet your expectations.

**Contact reference person:**

M. LAMBOT Michel - Client Care

Coris BioConcept

Science Park CREALYS

Rue Jean Sonet 4A

5032 - GEMBLOUX - BELGIUM

TEL : + 32(0)81.719.917

FAX : +32(0)81.719.919

e-mail : [client.care@corisbio.com](mailto:client.care@corisbio.com)

[www.corisbio.com](http://www.corisbio.com)

The undersign confirms that this notice has been notified the appropriate Regulatory Agency (AFMPS).

Signature

Coralie MISSON

QA Manager



CORIS BIOCONCEPT  
RUE JEAN SONET 4A  
BE-5032 GEMBLOUX

## CUSTOMER REPLY FORM

FSN reference number: **FSN\_NC2170**

**HAT Sero K-SeT**

**Product code: K-15S2**

**Lot number: 42874D2003**

Please complete and return this form by email ([client.care@corisbio.com](mailto:client.care@corisbio.com)) or by FAX (+32 81 719 919) as confirmation that you have received this notification before July 17, 2020.

### Acknowledgement of receipt

We have received the Field Safety Notice and have disseminated this information to our staff and to all relevant users and executed.

Facility name and address:	
Reply confirmation completed by:	
Title:	

Signature / date:  
REQUIRED FIELD

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Return acknowledgement to Client Care	
Email	<a href="mailto:client.care@corisbio.com">client.care@corisbio.com</a>
Postal Address	Coris BioConcept Science Park CREALYS Rue Jean Sonet 4A 5032 - GEMBLOUX - BELGIUM
Web Portal	<a href="http://www.corisbio.com">www.corisbio.com</a>
Tel :	+ 32(0)81.719.917
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