

Marburg, 2019-08-01

In-Field-Notification: Salivary Estrone ELISA, SLV-5228

Dear Customer,

This notice is to inform you about a quality issue with DRG's product **Salivary Estrone ELISA, SLV-5228**, lot # **98K019, 98K019-2**.

Description of the problem:

The user of these lots may determine higher percentage of samples with < 2.1 pg/mL for men and < 2.6 pg/mL for women. Saliva samples in the Normal Value range of the kit were generally assayed significantly lower (approx. 50%).

Therefore there is a possibility of inappropriate diagnosis.

This issue is caused by a component of calibrator's matrix that has lost activity over time. It was found with an incoming customer complaint and was not detected during our standardized production and QC process.

In case operators has used the kits of the affected lots, they may observe that

- optical densities (OD) of calibrators seem to be normal
- controls are in acceptance range and
- patients are lower than expected.

Corrective and preventive actions have been started already that prevent the re-occurrence of this error. Previous lots were checked and did not show this problem.

Risk assessment:

The Salivary Estrone ELISA (SLV-5228) is an enzymatic in vitro assay for the detection of Estrone in human saliva. Estrone levels are measured as an aid in fertility studies in women and to monitor Estrogen HRT. Fertility problems and HRT are not diagnosed on the outcome of Estrone alone but accompanied by other diagnostic test such as Estradiol.

Too low test results are associated with a medium to low risk. Either an unnecessary HRT with Estrogen in postmenopausal women could be applied, or an omitted therapy with antisteroids in women.

The likelihood for occurrence of such a condition is very low, however, because the error is discovered due to an increase of low values in the patient collective and due to conflicting clinical results; e.g. with Estradiol. The health risk for patients is minor in summary (temporary and reversible).

Action to be taken by distributors and end-users:

1. We kindly ask you to **immediately examine your stock and promptly quarantine** these products
2. Please send back or discard all unused kits
3. **Please use the attached response form, fill, sign and send back to us**
4. Please inform your customers and forward this notice to persons who received the affected lots
5. **Patient samples that have been determined with the affected lots should be checked again carefully.** If results are lower than expected samples should be re-run again.
6. Please tell us if you have experienced any problem with this lot and specify the details

Contact person for further information:

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With kind regards,
DRG Instruments GmbH

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To:	DRG Instruments GmbH
Fax:	+49 (0) 6421 1700-50
E-Mail:	raeder@drg-diagnostics.de
Re: product, lot #	Salivary Estrone ELISA, SLV-5228 Lot # 98K019, 98K019-2

Customer/Distributor name:	
Contact person:	
Phone number:	
E-Mail:	
Date / Signature	

Please check ALL appropriate box(es)

- I have read and understood the instructions in the letter dated August 01, 2019.
- I have checked my stock and have ___ product(s) on hold, of which ___ kits that need to be replaced.
- I have informed my end-users of this In-Field-Notification

Please check ALL boxes to describe your business

- Wholesale / Distributor
- Re-packer
- Hospital / Medical Facility
- Medical Laboratory

Please confirm the quantity of kits remaining at your facility for which you would require replacement:

Product, Description, Reference	Lot Number	Quantity of Products on stock or identified as contaminated	Quantity of requested kits

PLEASE RESPOND BY **August 15, 2019 AT LATEST TO:**

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