



桂林优利特医疗电子有限公司

URIT MEDICAL ELECTRONIC CO., LTD.

地址: 广西桂林市九华路东巷4号

邮编: 541001

ADD: NO.4 EAST ALLEY, JIUHUA ROAD, GUILIN GUANGXI 541001, P.R.CHINA

电话: +86 773 2832799 传真: +86 773 2804668 E-MALL: export@uritest.com

TEL: +86 773 2832799 FAX: +86 773 2804668 Http://www.uritest.com

Urgent Field Safety Notice

Commercial name of the affected product: Uritest 13G Urine Reagent Strips

FSCA-identifier: FSCA-20091209

Type of action: Advice given by manufacturer regarding the use of the device.

Return of the medical device to the supplier.

Date: 2009-12-09

Attention: importers/distributors and further to ending users

Detail on affected devices:

Uritest 13G Urine Reagent Strips

All batches

Description of the problem:

From the customers' feedback & the following inspection, we confirm that there's something problem with Uritest 13G urine reagent strips, which can be listed as follows:

1. Having a colour chart on the label may lead the users to misuse the product for visual use. Actually the lot No.20090227 and the earlier lot No. product label are only for reference, it can't be used to judge & confirm the testing result. Although the intended use with the product lot No. after lot No.20090227 notified to be visual use & analyzer mode use, however, from some users' feedback & the internal evaluation, we confirm that there's considerable risk to cause the false positive result according to the colour chart of microalbumin when it is for the visual use.
2. The sensitivity of Uritest 13G's microalbumin is 50-100mg/L, the testing results dividing into two levels, it is "negative" & " $\geq 100\text{mg/L}$ ", while the quantities of microalbumin testing as $\geq 50\text{mg/L}$ all reported as " $\geq 100\text{mg/L}$ ". The microalbumin cut-off point of Uritest 13G is 50mg/L, while the normal clinical cut-off point for microalbumin is 20mg/L. That means it is not so much clinical significance for the earlier screen of diabetic nephropathy etc.
3. There is the feedback from the users to state that it is not enough accuracy for the creatinine testing in this product. The investigation confirm that the creatinine is affected by the humidity to a great degree, if the bottle has been opened, but not be sealed back immediately, the pad mixing with the air for a long time may lead to the testing result of creatinine not correct.
4. The design requirement for the dipping length of this product should be longer than 100mm, exceeding the height of the normal urine sample pots in some areas' market. In this case, it can't make sure that the pad has been dipped in the urine totally.



桂林优利特医疗电子有限公司

URIT MEDICAL ELECTRONIC CO.; LTD.

地址: 广西桂林市九华路东巷4号

邮编: 541001

ADD: NO.4 EAST ALLEY, JIUHUA ROAD, GUILIN GUANGXI 541001, P.R.CHINA

电话: +86 773 2832799 传真: +86 773 2804668 E-MALL: export@uritest.com

TEL: +86 773 2832799 FAX: +86 773 2804668 Http://www.uritest.com

Advise on action to be taken by the user:

Regarding for the above problems of Uritest 13G urine reagent strips, the suggestions from us for you can be listed as follows:

1. As the visual function of this product is not perfect, please make sure not to use the Uritest 13G for visual use, it can be only used for the adaptive urine analyzer. The colour chart on the label is only for reference, it can't be used to judge & confirm the testing result.
2. Please pay attention to recognize the limitation in the microalbumin testing, if the sensitivity and tranches can't satisfy your test need, please use other product with the higher sensitivity and better function.
3. Because the stability of creatinine is affected by the humidity easily, please make sure that after taking out the urine strip for use every time, fasten down the base cover immediately, otherwise the testing result may be incorrect because of the long exposing time.
4. Our company can't do the improvement about the length & sequence of Uritest 13G, in consideration of the possibility of insufficient dipping, we remind you to make sure all the pads have been dipped totally while do the using.
5. If you have purchased the Uritest 13G urine reagent strips for visual use, or as the function of microalbumin can't meet your satisfaction, you could return back the goods to us via the local distributor or contact with us directly.

Please bring this notice to the attention of all personnel who need to be aware of this safety issue, including any organization where the affected products have been transferred.

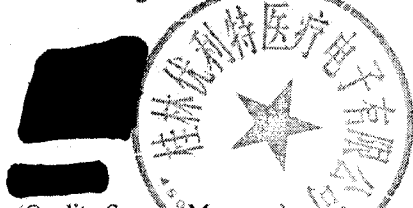
Please confirm receipt of this notice by completing the fax back from enclosed to:

+86(773)2804668 or +86(773)2288560.

URIT apologizes for the inconvenience this issue may cause. If you experience any problems complying with this notice or you require any other information please contact our Technical Support Department on +86(773)2288586 or through e-mail by service@uritest.com.

Sincerely,

The undersign confirms that this notice has been notified to the MHRA



(Quality System Manager)

URIT Medical Electronic Co., Ltd

No.4 East Alley, JiuHua Road, Guilin, Guangxi 541001, PR China

ACKNOWLEDGMENT OF RECEIPT TO BE FAXED

Fax number: +86(773)2804668 or +86(773)2288560

I undersigned, Mr., Mrs., Miss., Ms.....

Acknowledge receipt of the information from the company URIT Medical Electronic Co. Ltd related to the Uritest 13G urine reagent strips.

Please fill-in the information below:

Your company or organization information (Name, address & contact way):

.....
.....
.....

The product quantity & lot No. you request to feedback:

.....
.....
.....

Signature and Company stamp