Australian Government

Department of Health

Therapeutic Goods Administration

Recall Action Notification

STA R Max. An in vitro diagnostic medical device (IVD)

Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- **Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.**
- **More information about Australian recall actions is available at <**http://tga.gov.au/safety/recalls-about.htm**>**
- **If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <**http://www.healthdirect.org.au/**>**

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989. Copyright restrictions apply to the System of Australian Recall actions (SARA) <http://tga.gov.au/about/website-copyright.htm>.

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2021-RN-01433-1
Product Name/Description[iii]	STA R Max. An in vitro diagnostic medical device (IVD) Software version: 4.06 ARTG 184474 (Diagnostica Stago Pty Ltd - Instrument/analyser IVDs)
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	23/06/2021
Responsible Entity[vii]	Diagnostica Stago Pty Ltd
Reason / Issue[viii]	Customer feedback has highlighted an unusual frequency of abnormally shortened APTT (Activated partial thromboplastin time) clotting times on STA R Max instruments, since the software version 4.06 update. Stago investigation has identified an issue on “special” or “special plus” washes with STA-Desorb U on reagent needles (#2 and #3) when a level detection error (LLD) occurs. This washing anomaly is most commonly present in a specific context of non-recommended use (unloading and reloading of bottles of reagents already used, with entry of an incorrect residual volume by the user). If a LLD error appears on a test with a special wash, cross-contamination may occur with different test combinations.
Recall Action[ix]	Product Defect Correction
Recall Action Instructions[x]	Stago is advising customers that a software update, version 4.07.01, is available and will be installed shortly by a Stago representative. In the interim, users are recommended to not unload-reload reagents from the STA R Max before the end of the bottle. If this is necessary, ensure the correct entry of the residual volume is made when reloading a vial that has already been used and has not yet been completed.
Contact Information[xi]	03 9840 5555 - Vicki Guppy

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch /

serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- **Wholesale** - includes wholesalers and state purchasing authorities.
- **Hospital** - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- **Retail** - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- **Consumer** - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification**: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- **Class I** - A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death.
- **Class II** - A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
- **Class III**- A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences.

[vi] Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.

[ix] Recall Action**: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. There are four distinct recall actions – recall, product defect correction, hazard alert and product defect alert.

- **Recall** - The permanent removal of an affected therapeutic good from supply or use in the market.
- **Product defect correction** - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- **Hazard alert** - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.
- **Product defect alert** - Information issued to raise awareness about issues or deficiencies for a therapeutic good where a recall action will result in interruption of patient treatment or a medicine shortage, including advice to reduce potential risks of using affected goods.

[x] Recall Action Instructions: What customers with affected goods should do.

[xi] Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.

** These definitions are applicable to the 2017 URPTG (Implemented from Jan 15 2018). Recall Action types and Recall Action Classifications prior to 15 Jan 2018 can be found at:
https://www.tga.gov.au/sites/default/files/recalls-urptg-170412.pdf

Alla C.A. del responsabile del laboratorio

Milano, 22 giugno 2021

Riferimento: RC-21-0021

COMUNICAZIONE DI SICUREZZA

Versione software 4.06 dell'analizzatore STA R Max®

Caro Cliente,

Secondo quanto riportato nel nostro database, ad oggi lei utilizza un analizzatore STA R Max®. Qualora il suo strumento sia aggiornato alla versione software 4.06, la preghiamo di prendere attentamente visione di questa informativa sulla sicurezza riguardante possibili anomalie sul risciacquo dell'ago #2 e #3. Questa informativa non è rivolta ad utilizzatori di analizzatori STA R Max® che utilizzano una versione software precedente alla 4.06.

✓ Descrizione:

Abbiamo ricevuto alcune segnalazioni relative ad una insolita frequenza dei tempi di coagulazione del test APTT anormalmente ridotti, ottenuti su analizzatori STA R Max® aggiornati alla versione software 4.06.

In seguito ad una verifica interna è stato riscontrato un problema sul lavaggio "special" o "special +" con STA-Desorb U a carico degli aghi reagenti (#2 e #3), legato ad un errore di rilevamento del livello (LLD). Questa anomalia di lavaggio si riscontra comunemente nel caso di un utilizzo non raccomandato (scarico e successivo caricamento a bordo, con inserimento da parte dell'utilizzatore di un volume residuo errato, dei flaconi di reagenti già utilizzati).

Nel caso in cui si verifichi un errore LLD su un test che prevede un lavaggio speciale si può verificare una contaminazione incrociata con altri test.

Sulla base dell'analisi dei rischi da noi condotta il caso più critico riguarda la contaminazione del test APTT da parte del reagente del Fibrinogeno, con una conseguente riduzione significativa del tempo di coagulazione dell'APTT. Inoltre, essendo l'APTT e il Fibrinogeno test di routine, aumenta la probabilità che ciò si verifichi.

È possibile rilevare la riduzione del risultato del test APTT sul plasma di un paziente normale, il tempo ottenuto sarà infatti anormalmente breve (più breve del tempo di riferimento del laboratorio). Al contrario, potrebbe essere difficile rilevare la riduzione di un APTT sul plasma di un paziente patologico.

✓ Azioni:

Una nuova versione software è già disponibile: la versione 4.07.01 verrà installata a breve dal rappresentate Stago.

In attesa che il suo analizzatore venga aggiornato, al fine di limitare il rischio di un errore LLD dei reattivi, le raccomandiamo di non scaricare e successivamente ricaricare a bordo dell'analizzatore STA R Max® reattivi non ancora esauriti.

Nel caso ciò si renda necessario, le raccomandiamo di assicurarsi di inserire il valore di volume residuo al momento di caricare nuovamente a bordo un flacone che è già stato utilizzato ma che non è ancora esaurito.
Questa procedura consentirà una gestione ottimale dei volumi da parte dell'analizzatore e quindi di evitare il rischio che l'anomalia descritta si verifichi.

Sulla base dell'analisi dei rischi da noi condotta, considerato che i risultati dei pazienti sono interpretati in un contesto clinico-biologico globale, se non avete scaricato-ricaricato i reagenti a bordo del vostro STA R Max® senza inserire l'esatto volume residuo, è improbabile che questo difetto si sia verificato o che possa avere conseguenze dannose per la salute del paziente. Di conseguenza, non è necessario rivedere i risultati dei pazienti precedenti.

La preghiamo di restituire, via fax o via e-mail, al suo rappresentante Stago il modulo allegato correttamente compilato a conferma di aver letto questa informativa e dell'impegno ad applicare le istruzioni in essa contenute.

L'autorità amministrativa competente del paese d'origine (Francia), così come quella locale di competenza sono state informate in merito a tale Comunicazione di Sicurezza.

Per ulteriori informazioni, si prega di contattare il proprio rappresentante Stago.

La preghiamo di accettare le nostre scuse per questo inconveniente. La ringraziamo in anticipo per il vostro supporto.

Distinti saluti,