Field Safety Notice

SBN-RMD-2018-001

RMD / MagNA Pure 24 Instrument
Version 3
02-Jul-2018

Updated: MagNA Pure 24 Instrument Cross Contamination – Pathogens Protocol

Product Name	MagNA Pure 24 System
GMMI / Part No **Device Identifier**	GMMI: 07290519001 Device Identifier: 07613336106174
Production Identifier (Lot No./Serial No.)	N.A
SW Version	N/A
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

As previously communicated, there was a potential for cross contamination when using the specific Pathogen 200 and Pathogen 1000 protocols with the MagNA Pure 24 System due to a too low offset value for the Magnetic Glass Particle (MGP) pre-dispensing to the reagent wells of the processing cartridge. The protocols have been updated to mitigate the situation, and are now available. Installation of these protocols (Pathogen 200 and Pathogen 1000 Version 2.0) is mandatory and needs to be completed by 30-Sep-2018.

Actions taken by Roche Diagnostics

Roche Service Representatives will perform the installation of the updated Pathogen 200 and Pathogen 1000 protocols Version 2.0.

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MagNA Pure 24 Instrument Cross Contamination – Pathogens Protocol

Communication of this Field Safety Notice

This notice must be passed on to all those who need to be aware within your organization or to any other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA.

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

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

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