FSN Ref: 2025-12

Date: 19-12-2025

Urgent Field Safety Notice
NGSengine

For Attention of*:Users of products NGSengine v 4.0, v 4.0.2, v 4.1 in combination with NGSgo-ProntoAmp

Contact details of local representative (name, e-mail, telephone, address etc.)*
Genome Diagnostics B.V (GenDx) regulatory@gendx.com T +31 (0)30 252 3799 Yalelaan 48 3584 CM, Utrecht The Netherlands

Urgent Field Safety Notice (FSN)
NGSengine

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	NGSengine
1.	2. Commercial name(s)
	NGSengine
1.	3. Unique Device Identifier(s) (UDI-DI)
	(01)08718469360642
1.	4. Primary clinical purpose of device(s)*
	NGSengine is a qualitative in vitro diagnostic software product intended for high-resolution identification of HLA alleles by means of sequencing-based typing (SBT). Specimens are Next-Generation Sequencing (NGS) data files, derived from HLA amplicons, originated from human genomic DNA. NGSengine is non-automated software, intended to inform clinical management as an aid in the diagnosis of HLA gene compatibility between donor and recipient for transplantation purposes (e.g. hematopoietic stem cell transplantation). The intended testing population are both, transplant donors as well as transplant recipients. NGSengine is intended for laboratory professional use in an EFI or ASHI accredited diagnostic laboratory setting, by personnel trained in HLA typing and DNA sequencing.
1.	5. Device Model/Catalogue/part number(s)*
	4949940, 4949740, 4949840, 4949640
1.	6. Software version
	v 4.0, v 4.0.2, v 4.1
1.	7. Affected serial or lot number range
	n/a
1.	8. Associated devices
	NGSgo-ProntoAmp and NGS-ProntoPrep

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	In case of a novel HLA null allele with an insertion or deletion (InDel) within a repetitive coding region, and sequenced on a nanopore sequencing platform, the InDel may be aligned across multiple positions. As a result, for such novel alleles, the signal appears as high noise rather than a heterozygous call. This may result in reporting an incorrect best match HLA typing in analysing software NGSengine.
2.	2. Hazard giving rise to the FSCA*
	A known HLA variant is reported instead of a new HLA null allele.
2.	3. Probability of problem arising
	The estimated frequency of this situation is very low (0,045%). New null alleles are not frequently found and are unlikely to be common in the population. In addition, the new null allele needs to have an Indel in a repeat region.
	4. Predicted risk to patient/users

2.	Low. Incorrect HLA typing can lead to delayed transplantation, graft-versus-host disease, or development of HLA-specific antibodies. Probability of new null alleles with InDel in repetitive coding region is very low.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None • The user should take note of the advisory notice (“Advisory Notice: NGSengine in combination with NGS-Pronto and NGS-Turbo”) sent by email (December 19 2025). • Download the updated IFU NGSengine edition 10 from the GenDx website https://www.gendx.com/ifu2/	
3.	2. By when should the action be completed?	Completed Customer Reply to be returned January 16 2026
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients’ previous results recommended? No Likelihood of encounter the issue is very low	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☒ IFU or labelling change ☐☒ Other ☐ None - An advisory notice was sent (December 19, 2025) to users to explain and provide guidance on the situation.	
3	6. By when should the action be completed?	Advisory notice and IFU update by December 24 2025, Software upgrade aimed by March 2026
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	n/a
4.	**3.** For Updated FSN, key new information as follows:	
	n/a	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	n/a	
4	6. Anticipated timescale for follow-up FSN	n/a
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Genome Diagnostics B.V. (GenDx)
	b. Address	Yalelaan 483584 CM, Utrecht.The Netherlands
	c. Website address	GenDx.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Insert Name and Title here and signature below

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.