

Medicines and Healthcare products Regulatory Agency - <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

Field Safety Notices: 29 November to 3 December 2021 - <https://www.gov.uk/drug-device-alerts/field-safety-notices-29-november-to-3-december-2021>

List of field safety notices (FSNs) from medical device manufacturers from 29 November to 3 December 2021

Published 6 December 2021

List of FSNs published since January 2020 (filtered to display "SARS" in Device description) - <https://mhra.gov.filecamp.com/s/xTvGS79gIPBvG6g9/d>

Manufacturer	Brand	Date or reference on FSN	Device description	MHRA reference	Date added to gov.uk
QIAGEN	QIAstat-Dx Respiratory SARS-CoV-2 Panel	30 December 2020	IVDs, SARS-CoV-2 instrumentation antigen test	<a href="#">2020/012/030/487/001</a>	04/01/2021
Beckman Coulter	Access SARS-CoV-2 IgG Quality Control	6 January 2021	IVDs, SARS-CoV-2 antibody immunoassa	<a href="#">2021/001/008/601/005</a>	18/01/2021
DNAudge	CovidNudge DnaCartridge	22 December 2020	IVDs, SARS-CoV-2 PCR test	<a href="#">2020/012/021/601/003</a>	18/01/2021
DNAudge	CovidNudge DnaCartridge	4 January 2021	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/001/004/601/002</a>	18/01/2021
LumiraDx	LumiraDx SARS-CoV-2 Ag Test Strip Kit	03 February 2021	IVDs, SARS-CoV-2 Instrumentation antigen test	<a href="#">2021/002/016/601/006</a>	22/02/2021
Ortho Clinical Diagnostics	VITROS SARS-CoV-2 Antigen Reagent	CL2021-064_EU	IVDs, SARS-CoV-2 Antibody Immunoassay	<a href="#">2021/002/018/601/005</a>	22/02/2021
ThermoFisher	Applied Biosystems COVID-19 CE-IVD Int. SW	3 March 2021	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/003/003/701/025</a>	08/03/2021
LumiraDx	SARS-CoV-2 Ag Test Strip Kit	2 March 2021	IVDs, SARS-CoV-2 Instrumentation antigen test	<a href="#">2021/002/018/601/006</a>	15/03/2021
Eurofins Forensic Services	Eurofins	2 April 2021	VDs, SARS-CoV-2 PCR test	<a href="#">2021/003/031/291/001</a>	19/04/2021

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Medical Wire & Equipment	Dryswab	20 April 2021	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/004/021/291/001</a>	26/04/2021
Bosch Healthcare	SARS-CoV-2 and SARS-CoV-2 Pooling	10 May 2021	SARS-CoV-2 PCR Test	<a href="#">2021/005/013/291/006</a>	17/05/2021
Beckman Coulter	SARS-CoV-2 IgG II Reagent and Calibrator	20 May 2021	IVDs, SARS-CoV-2 antibody immunoassay	<a href="#">2021/005/021/601/004</a>	31/05/2021
Medical Wire & Equipment	Dryswab	11 June 2021	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/006/014/601/500</a>	28/06/2021
Primerdesign	PROmate™ COVID-19 [Primerdesign Ltd (Novacyt Group)] Real-Time PCR IVD test for genesig® q16 qPCR platform	30 March 2021	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/004/026/601/513</a>	28/06/2021
Wuxi Nest Biotechnology	Wuxi Nest swab	20 July 2021	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/007/029/601/002</a>	02/08/2021
Roche Diagnostics	cobas® SARS-CoV-2 & Influenza A/B	SBN-RDS-POC-2021-010	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/007/030/487/003</a>	09/08/2021
SureScreen Diagnostics	Antigen Rapid Test	29 July 2021	IVDs, SARS-CoV-2 lateral flow antigen test	<a href="#">2021/007/029/601/005</a>	09/08/2021
Novacyt Group	PROmate COVID-19 assay/q16 instrument /software version 2.10.3	23 July 2021	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/007/028/601/503</a>	23/08/2021

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Qiagen	QIAstat-Dx Respiratory SARS-CoV-2 Panel	23 August 2021	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/008/025/291/003</a>	06/09/2021
Abbott	Alinity m SARS-CoV-2 AMP Kit & Alinity m Resp-4-Plex Amp Kit	2 September 2021	IVDs, SARS-CoV-2 PCR Test	<a href="#">2021/009/006/487/005</a>	18/10/2021
Primerdesign	Genesig® Real-Time PCR Coronavirus COVID-19 CE IVD kit	28 June 2021	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/010/005/601/002</a>	18/10/2021
RT Diagnostics	COVID-19 PCR Sampling Kits	14 September 2021	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/009/027/601/505</a>	18/10/2021
Thermo Fisher	TaqPath™ Covid-19 CE-IVD RT-PCR Ki	PR#518365	IVDs, SARS-CoV-2 PCR Tes	<a href="#">2021/011/010/579/007</a>	22/11/2021
Abbott	ID NOW COVID-19 24 Test Kit	27 October 2021	IVDs, SARS-CoV-2 PCR test	<a href="#">2021/011/008/601/501</a>	29/11/2021