Probability					
(P5)Very High	II	II	I	I	I
(P4)High	II	II	II	I	I
(P3)Moderated	III	II	II	II	I
(P2)Low	III	III	II	II	II
(P1)Very Low	III	III	III	II	II
	(S1)Very Low	(S2)Low	(S3)Moderated	(S4)High	(S5)Very High

Severity

Probability ranking

P1	improbable	Hardly any cases known	1-2 tests/1,000,000
P2	remote	Several cases per year	1-9 tests/100,000
P3	occasional	Several cases per months	1-9 tests/10,000
P4	probable	May occur during use of the product	1-9 tests/1000
P5	frequent	Occurs very frequently during use of the product	1-9 tests/100

Severity ranking

S1	negligible	No damage, minor damage
S2	minor	damage reversible, damage can be compensated
S3	serious	damage that requires medical treatment but no permanent health threat
S4	critical	Severe health damage
S5	catastrophic	Losses of Lives

The risk level

The risk level is represented by a scale going from I to III, The highest risk is represented by risk I and the lowest by III.
After a deployed CAPA the only acceptable level risks are Risk II (if benefice > risk) and Risk III. No risk I should persist in the residual risk.

Risk I: The risk is at an unacceptable level and a CAPA (Corrective action / Preventive action) must be deployed in order to bring the risk to an acceptable level (Risk II or Risk III)
Risk II: The risk is at an acceptable level if benefice > risk.
Risk III: The risk is the lowest one and is considered as acceptable.

Classification	NF EN ISO 14971:2012 Annex H	Hazardous situation Annexe H.2.5+G	Foreseeable hazard/ phenomene dangereux Annexe H.2.4	Possible effect (result)	Potential cause	Initial Risk level	Risk control measure CAPA	New hazard introduced ?	Residual Risk level	Residual risk acceptable?
H1 - Ordering material	na	planning batch size	planning the incorrect quantity to be made	not able to meet customer needs or having excess waste	incorrect computer enter	S1P3	computer program-demand solutions	No	S1P1	Risk III - acceptable
H1 - Ordering material	na	improper assigning lot numbers	assigning the wrong part number	wrong product made-creating waste-delay in production	untrained personnel	S1P1	training and work order is double checked by material controller	No	S1P1	Risk III - acceptable
H1 - Ordering material	na	improper assigning lot numbers	assigning a duplicate lot number	misidentified product-delay in production	untrained personnel	S1P1	training and work order is double checked by material controller	No	S1P1	Risk III - acceptable
H1 - Ordering material	na	improper assigning lot numbers	assigning the wrong expiration date	expired product could be shipped to customer leading to incorrect results	untrained personnel	S1P1	training and work order is double checked by material controller	No	S1P1	Risk III - acceptable

Classification	Manufacturing step	NF EN ISO 14971:2012 Annex H	Hazardous situation Annexe H.2.5+G	Foreseeable hazard/ phenomene dangereux Annexe H.2.4	Possible effect (result)	Potential cause	Initial Risk level	Risk control measure CAPA	New hazard introduced ?	Residual Risk level	Residual risk acceptable?
H2 - Test production	Raw material	na	False results	False results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	Incorrect critical raw material used	S3P2	Design & Development Control (QSP-1000) require product testing, verification & validation; incoming QC inspection must be done (QSP-2100)	No	S3P1	Risk III acceptable
H2 - Test production	Raw material	na	False results	False results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	Inadequate stability of the raw materials	S3P2	Qualification of alternate suppliers if possible (QSP-1200), appropriate QC inspection criteria (QSP-2100). Stability testing should be done.	No	S3P1	Risk III acceptable
H2 - Test production	Raw material	na	False results	False results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	The quality of the antigen does not produce the expected performance	S3P2	Design control require verification and validation (QSP-1000). Incoming QC inspection documents (QSP-2100)	No	S3P1	Risk III acceptable
H2 - Test production	Raw material	na	False results	False results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	The sample pad does not conform to specifications	S3P2	Manufacture Process Control Procedure (QSP-1400), Incoming QC inspection documents (QSP-2100), and Manufacture SOPs	No	S3P1	Risk III acceptable
H2 - Test production	Manufacturing	na	False results	False results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	Operator not following manufacturing procedures	S3P2	C line solution, T line solution, Label pad manufacturing SOPs & QC inspection documents; training procedures (QSP-2600)	No	S3P1	Risk III acceptable
H2 - Test production	Raw material	na	False results	False results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	Bad adhesive ability of the component (deviation from specifications)	S3P2	IQC-0020 (White Polystyrene Backing Splits Inspection Specification)	No	S3P1	Risk III acceptable

Classification	Manufacturing step	NF EN ISO 14971:2012 Annex H	Hazardous situation Annexe H.2.5+G	Foreseeable hazard/ phenomene dangereux Annexe H.2.4	Possible effect (result)	Potential cause	Initial Risk level	Risk control measure CAPA	New hazard introduced ?	Residual Risk level	Residual risk acceptable?
H2 - Test production	Raw material	na	holes in membrane, membrane flaked off, irregularities in membrane quality	Insufficient chromatography due to mechanical damage of membrane, disturbed flow rate	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures Invalid result: user needs another test	defective raw material (membrane)	S3P3	In process and final QCs: Control of incoming products at Biosynex: visual control of membrane integrity and good capillary flow. Lot will be rejected and shipped back in case of non conformity.	No	S3P2	Risk II (benefit> risk) - acceptable
H2 - Test production	Lines C and T Vaporisation	na	No control line - invalid test line	No control line - invalid test line	user needs another test	production error- improper striping of the nitrocellulose membrane	S1P2	Correct function of the test checked during in process and final QCs; Control of incoming products at Biosynex. No control line means invalid test result (user control).	No	S1P1	Risk III acceptable
H2 - Test production	Lines C and T Vaporisation	na	False results - reversed control/test lines	False results - reversed control/test lines	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	production error- improper striping of the nitrocellulose membrane (reversed control/test lines)	S3P2	Correct function of the test checked during in process and final QCs; Control of incoming products at Biosynex.	No	S3P1	Risk III acceptable
H2 - Test production	Conjugate Vaporisation	na	Contamination - false results	Contamination - false results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	production error - improper conjugate pad soaking/spraying (contamination)	S3P2	Correct function of the test checked during in process and final QCs; Control of incoming products at Biosynex.	No	S3P1	Risk III acceptable
H2 - Test production	Card assembling	na	improper strip assembly	inverted conjugate pad	False negative result: patient not treated - no isolation measures taken, patient might infect other persons	production error	S3P2	Correct function of the test checked during in process and final QCs; Control of incoming products at Biosynex.	No	S3P1	Risk III acceptable
H2 - Test production	Card assembling	na	improper strip assembly	too much overlap	improper flow/flooding - invalid result - user needs another test	production error	S1P2	Correct function of the test checked during in process and final QCs; Control of incoming products at Biosynex.	No	S1P1	Risk III acceptable
H2 - Test production	Card assembling	na	improper strip assembly	no test strip	no result - invalid result - user needs another test	production error	S1P2	Correct function of the test checked during in process and final QCs; Control of incoming products at Biosynex.	No	S1P1	Risk III acceptable
H2 - Test production	Card assembling	na	improper strip assembly	test strip misaligned	no result - invalid result - user needs another test	production error	S1P2	Correct function of the test checked during in process and final QCs; Control of incoming products at Biosynex.	No	S1P1	Risk III acceptable
H2 - Test production	Card assembling	na	improper strip assembly	test strip upside-down	no result - invalid result - user needs another test	production error	S1P2	Correct function of the test checked during in process and final QCs; Control of incoming products at Biosynex.	No	S1P1	Risk III acceptable
H2 - Test production	Card assembling	na	improper strip assembly	device not closed tightly	sample leak - contamination of the user or patient	production error	S4P2	Correct function of the test checked during in process and final QCs; Control of incoming products at Biosynex.	No	S4P1	Risk II (benefit> risk) - acceptable
H2 - Test production	Card assembling	na	improper strip assembly	component missing	no result	production error	S1P2	Correct function of the test checked during in process and final QCs; Control of incoming products at Biosynex.	No	S1P1	Risk III acceptable

Classification	Manufacturing step	NF EN ISO 14971:2012 Annex H	Hazardous situation Annexe H.2.5+G	Foreseeable hazard/ phenomene dangereux Annexe H.2.4	Possible effect (result)	Potential cause	Initial Risk level	Risk control measure CAPA	New hazard introduced ?	Residual Risk level	Residual risk acceptable?
H3 - Assembling cassette	Cassette assembling	na	False results	False results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	Incorrect test is assembled	S3P3	Manufacturing SOPs & QC inspection documents, Final QC	No	S3P1	Risk III acceptable
H3 - Assembling cassette/stylo	Cassette assembling	na	improper device assembly while placing the strip in the cassette	during strip cutting, the membrane could break	invalid result - user needs another test	operator error	S1P2	QC inspection	No	S1P1	Risk III acceptable
H3 - Assembling cassette/stylo	Cassette assembling	na	improper device assembly while placing the strip in the cassette	device not closed properly	invalid result/no flow - user needs another test	operator error	S1P2	QC inspection	No	S1P1	Risk III acceptable
H3 - Assembling cassette/stylo	Cassette assembling	na	improper device assembly while placing the strip in the cassette	device not closed properly	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	operator error, slow flow rate	S3P2	QC inspection	No	S3P1	Risk III acceptable

Classification	Manufacturing step	NF EN ISO 14971:2012 Annex H	Hazardous situation Annexe H.2.5+G	Foreseeable hazard/ phenomene dangereux Annexe H.2.4	Possible effect (result)	Potential cause	Initial Risk level	Risk control measure CAPA	New hazard introduced ?	Residual Risk level	Residual risk acceptable?
H4 - Hazard due Packaging/labelling failure	Pouching	na	False results	False results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	Desiccant is missing	S3P2	QSR-2107 (Desiccant Inspection Specification), Final QC	No	S3P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Labelling	na	False results	False results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	The labeling is altered or lost	S3P2	Manufacturing SOPs & QC inspection documents, Final QC	No	S3P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Pouching	na	improper device pouching	no device included	customer dissatisfaction	operator error	S1P3	Line clearance, QC inspection	No	S1P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Pouching	na	improper device pouching	no dessicant	moisture on membrane potentially causing false + False positive result: patient inappropriately submitted to isolation measures	operator error	S3P2	Line clearance, QC release	No	S3P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Pouching	na	Improper dessicant	Pillow pack not intact: SiO_2 balls spilled in pouch	Effect on test not known – most likely test performance would not be influenced adversely, No harm for user	raw material not suitable	S1P2	Control of incoming products. Lot will be stopped and shipped back if broken pillow packs are noticed during QC	No	S1P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Pouching	na	Improper pouch sealing	Bad sealing of pouch	reducing the shelf-life of device due to humidity which might lead to false results - False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	equipement failure	S3P2	Qualification of sealing equipment	No	S3P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Pouching	H2.4.3	Improper pouch labelling	Incorrect lot#	Traceability not ensured	operator error	S3P2	Quality inspection	No	S3P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Pouching	H2.4.3	Improper pouch labelling	Incorrect expiry date	Traceability not insured. Test might be used although already expired which might lead to false results - False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	operator error	S3P2	Quality inspection	No	S3P1	Risk III acceptable

H4 - Hazard due Packaging/labelling failure	Pouching	H2.4.3	Improper pouch labelling	Markings not complete: manufacturer, symbols for single use, IVD, read user instruction, storage conditions and CE not complete	User misses important information which might lead to product misuse	defective printing on the pouch	S3P2	Control of incoming products ensures that symbols on the pouch are correct and complete. All information given on the pouch as symbol are also in the IFU in wording and symbol. Lot will be stopped and shipped back it cannot be corrected in house.	No	S3P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Pouching	H2.4.3	Improper pouch labelling	Test name not printed on the pouch	User might mix up tests with others and does not know intended use.	defective printing on the pouch	S3P2	Control of incoming products ensures correct imprint. Product name also clearly visible from imprint on test cassette, from label on cardboard box and from supplied IFU. Lot will be stopped and shipped back if cannot be corrected in house, no additional measures required.	No	S3P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Liquid filling	na	Severe mechanical forces on buffer bottle	Cracked/ not tightly closed dropper bottle	Leaking of irritant liquid. Not sufficient volume left to perform assays.	equipement failure	S3P1	In process QC, incoming product QC at Biosynex. Warning in IFU to wear gloves and protective clothing. IFU states to rinse skin or eyes with ample volume of water in case of contact with the solution.	No	S3P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Solution packaging (diluant/lavage/conjugué/contrôle positif)	H2.4.3	Wrong labelling of dropper bottles	Misinformation of user	Mixing up the buffer with other tests, which might lead to false results: False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	equipement failure	S3P1	Visual control of incoming product at Biosynex. Lot will be stopped and shipped back if it cannot be corrected in house.	No	S3P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Packaging	na	Swab package damaged	Not sterile due to damaged packaging	Minor Infectious risk	equipement failure	S2P2	Sterility of the swab is under the responsibility of its legal manufacturer (CE marking CE 0197 - CE certificate available) Swab pouch indicates not to use the product if package is damaged	No	S2P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Packaging	H2.4.3	kit contents	insufficient quantity or Package insert forgotten	user is unable to run assay	production error	S1P2	QC inspection	No	S1P1	Risk III acceptable
H4 - Hazard due Packaging/labelling failure	Packaging	H2.4.3	incorrect kit label	incorrect kit label	mislabeled product - user misses important information which might lead to product misuse	operator error	S2P2	Training of operators. In process QC and final visual QC.	No	S2P1	Risk III acceptable

H4 - Hazard due Packaging/labelling failure	Packaging	H2.4.3	incorrect printing of batch number and expiry date	incorrect printing of batch number and expiry date	Lack of traceability User uses an expired product which might lead to false results: False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	operator error	S2P2	Training of operators. In process QC and final visual QC.	No	S2P1	Risk III acceptable

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H5 - Hazards caused by biological and chemical	na	The buffer contains irritant substance (sodium azide)	The buffer contains irritant substance (sodium azide)	Mild irritation of skin or eyes of the user	Contact between skin or eyes of the user and buffer	S3P2	Warning in the IFU that the user must wear protective clothing and gloves. The buffer is packaged in a bottle with dropper cap that avoid spillage.	No	S3P1	Risk III acceptable
H5 - Hazards caused by biological and chemical	na	The buffer contains dangerous substance (sodium azide)	The buffer contains dangerous substance (sodium azide)	Solution with sodium azide might react with lead or copper plumbing.	Contact between buffer and lead or copper plumbing	S3P2	Warning included in the IFU: solutions eliminated in a sink must be rinced with ample volumes of water.	No	S3P1	Risk III acceptable
H5 - Hazards caused by biological and chemical	na	Sample is potentially infectious	Sample is potentially infectious	Infection of the user	Contact between the user and the sample	S3P2	As the test is carried out by professional lab personal that is trained in the handling of potentially infectious specimen. the risk of an infection can be considered as low. Warnings for safe handling of the sample are given in the IFU.	No	S3P1	Risk III acceptable
H5 - Hazards caused by biological and chemical	na	Sample is potentially infectious	Waste disposal is not secure	Personnal exposed to infectious specimen	User error	S3P1	Clear instructions are given in the IFU that precautions must be taken in collecting, handling, storing, and disposing specimen.	No	S3P1	Risk III acceptable

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H6 - environnmental hazard	na	False results	False results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	The raw material storage conditions not correct	S3P2	The shelf life of the raw material should be defined in COA from vender and validated by R&D during the product development; Manufacturing SOPs	No	S3P1	Risk III acceptable
H6 - environnmental hazard	na	Inappropriate warehouse storage condition for uncut sheet (semi finished goods)	reduced functioning product	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures Invalid result: user needs another test	untrained personnel/malfunction of temperature control device	S3P2	staff is trained and the semi finished goods are stored under controlled conditions.	No	S3P1	Risk III acceptable
H6 - environnmental hazard	na	Inappropriate warehouse storage condition for finished goods	reduced functioning product	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures Invalid result: user needs another test	untrained personnel/malfunction of temperature control device	S3P2	Training of staff. Controlled temperatures for the storage of goods.	No	S3P1	Risk III acceptable
H6 - environnmental hazard	na	Inappropriate warehouse storage condition for controls and panels	Controls or panels do not perform as expected	QC result is inaccurate - potential release of defective batch which might lead to false results; False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	untrained personnel / temperature control malfunction	S3P2	Training of staff. Controlled temperature for the storage of controls and panels	No	S3P1	Risk III acceptable
H6 - environnmental hazard	H.2.2.2 H.2.4.4	user inappropriate sample storage	stored too long	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	Instructions for the storage of specimen are described in the IFU	No	S3P1	Risk III acceptable
H6 - environnmental hazard	H.2.2.2	user inappropriate sample storage	wrong temperature	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	Instructions for the storage of specimen are described in the IFU	No	S3P1	Risk III acceptable

H6 - environmental hazard	H.2.2.2	user inappropriate kit storage	wrong temperature	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	Instructions for the storage of test device are described in the IFU	No	S3P1	Risk III acceptable
H6 - environmental hazard	H.2.2.2	user inappropriate kit storage	test cassette stored outside the pouch, so that the device is exposed to inappropriate humidity conditions	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	Instructions for the storage of test device are described in the IFU	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	long time exposure to ambient air after opening the pouch	long time exposure to ambiant air after opening the pouch	reduced device performance because of humidity - false results: False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	Relevant instruction stated in the IFU	No	S3P1	Risk III acceptable
H6 - environmental hazard	na	inappropriate transport conditions (temperature too high or too low)	inappropriate transport conditions (temperature too high or too low)	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	poor transportation conditions	S3P2	Instructions for the storage of test device are described in the IFU	No	S3P1	Risk III acceptable
H6 - environmental hazard	na	kit damaged during transport	end user obtained an inconclusive result/no flow	Invalid result: user needs another test	poor transportation conditions	S1P2	Kits are packed to ensure minimal damage. In addition the package insert states to repeat test if test is invalid.	No	S1P1	Risk III acceptable

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H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	user inappropriate sample volume (sample extracted in the buffer)	too much sample	flooding - no results - user needs another test	user error - too much sample placed on the test cassette	S3P2	Procedure for sample collection and preparation is detailed in the IFU. Illustrations are added to simplify the reading and the understanding of this procedure. Availability of a video explaning the procedure and of a simplified user guide.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	user inappropriate sample volume (sample extracted in the buffer)	insufficient volume of sample	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures invalid test results - user needs another test	user error - insufficient volume of sample placed on the test cassette	S3P2	Procedure for sample collection and preparation is detailed in the IFU. Illustrations are added to simplify the reading and the understanding of this procedure. Availability of a video explaning the procedure and of a simplified user guide.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	wrong sample type used	wrong sample type used	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error - wrong sample type used	S3P2	IFU clearly indicated the sample type to be used.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Poor quality of swab extraction	Poor quality of swab extraction	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	IFU clearly indicates the procedure for the extraction of the swab in the buffer	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Poor quality of sample collection	Poor quality of sample collection	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error - user not qualified	S3P2	Procedure for sample collection is described in the IFU	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Re-use of the kit components (swab, cassette, extraction tube)	Re-use of the kit components (swab, cassette, extraction tube)	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P1	Swab, cassette, extraction tubes are for single use. Pictogram on the pouch and the kit indicates that condition.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	long time exposure to ambiant air after opening the pouch	long time exposure to ambient air after opening the pouch	reduced device performance because of environmental conditions - False negative result: patient not treated - no isolation measures taken, patient might infect other persons/ False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	Relevant instruction stated in the IFU	No	S3P1	Risk III acceptable

H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	improper testing method	improper testing method	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error - non respect of the test procedure	S3P2	IFU states as limitation that the non-respect of the described test procedure might lead to false or invalid results	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Confusion between test line and control line	Confusion between test line and control line	invalid test results - user needs another test False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	Control and test lines are identified on the test cassette by marking of letters C and T. In addition IFU shows device orientation relative to sample well. The interpretation is illustrated in the IFU. Availability of a video explaning the procedure and of a simplified user guide.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Use error - wrong rapid test used	Use error - wrong rapid test used	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	The name of the test is written on the pouch and the cassette.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Use error - wrong reading time	If the result is read to early weak positive results that develop only after 15 min would be overlooked. False negative result would be the consequence. After 20 min, risk that the test line will appear even in case of negative specimen.	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	Reading time is stated in the IFU. A reading time flex study was performed and showed that the product can accomodate a fluctuation of the reading time to 15-20 minutes.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.3	User error	Using the result of the IVD assey for a new clinical intention that has not been approved by the manufacturer of the test	patient incorrectly diagnosed. Not meeting the package insert claims	user error	S4P1	The intended use is clearly stated in the instructions for use – the test is only used as an aid in diagnosis	No	S4P1	Risk II acceptable (benefit > risk)
H7 - Hazard related to using the test	H.2.2.3	User error - mixing up the components of different kit batches	User error - mixing up the components of different kit batches	Lack of traceability of components used	user error	S1P3	Warning included in the IFU: components must not be exchanged or mixed between different batches	No	S1P2	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.3	User error - overlooking faint lines	User error - overlooking faint lines	Test interpreted as negative whereas it is positive - patient not treated - no isolation measures taken, patient might infect other persons	user error	S3P3	Warning included in the IFU: any shade of color of the T line must be considered positive	No	S3P2	Risk II acceptable (benefit > risk)
H7 - Hazard related to using the test	NA	User error: Hand or airborne contamination	User error: Hand or airborne contamination	False positive result: patient is inappropriatly submitted to isolation measures	user error / not following GLP	S3P3	Warning included in the IFU: change gloves before collecting a new sample and performing a new test; do not take out the components from the kit after collecting a sample without removing gloves and disinfecting your hands; perform the sample collection and the test procedure in well-ventilated rooms	No	S3P2	Risk II acceptable (benefit > risk)
H7 - Hazard related to using the test	NA	User error: environmental conditions for the realization of the test are not adequate (not following instructions for use)	User error: environmental conditions for the realization of the test are not adequate (not following instructions for use)	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P3	Warning included in the IFU that inadequate humidity and/or temperature conditions may lead to false results	No	S3P2	Risk II acceptable (benefit > risk)

H7 - Hazard related to using the test	NA	User error: utilisation of specimen stored in saline solution or in viral transport medium	User error: utilisation of specimen stored in saline solution or in viral transport medium	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P3	Warning included in the IFU: The use of specimens stored in transport medium or saline may adversely affect the results. Use only freshly collected samples using the provided swabs	No	S3P2	Risk II acceptable (benefit > risk)

Classification	NF EN ISO 14971:2012 Annex H	Hazardous situation Annexe H.2.5+G	Foreseeable hazard/ phenomene dangereux Annexe H.2.4	Possible effect (result)	Potential cause	Initial Risk level	Risk control measure CAPA	New hazard introduced ?	Residual Risk level	Residual risk acceptable?
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	inappropriate extracted sample solution volume	too much extracted sample solution	flooding migration problem invalid result - user needs another test	user error	S1P3	Instruction on volume is emphasised in bold and in color in the leaflet Correct handling of the device and understanding of the IFU by the layuser verified in the layuser study.	No	S1P3	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	inappropriate extracted sample solution volume	insufficient extracted sample solution	flooding migration problem invalid result - user needs another test	user error	S1P2	Instruction on volume is emphasised in bold and in color in the leaflet Correct handling of the device and understanding of the IFU by the layuser verified in the layuser study.	No	S1P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	inadequate nasal sample collection	poor quality of the sample	False negative result: patient not treated - no isolation measures taken, patient might infect other persons	user error	S3P4	Detailed instructions and illustrations in the leaflet. Video explaining the sample collection procedure.	No	S3P3	Risk II acceptable (benefit > risk)
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Use errors by layman	Reuse of device	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	Kits are for single use. Pictogram in the kit and leaflet indicates that condition.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Use errors by layman	long time exposure to the air after tearing the pouch	decrease of device performance because of humidity: False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	The test must be used within one hour as instructed in the leaflet. Correct handling of the device and understanding of the IFU by the layuser verified in the layuser study.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Use errors by layman	Improper testing method/Non respect of user procedure	invalid result - user needs another test False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P3	Put corresponded notice phrase in IFU. Correct handling of the device and understanding of the IFU by the layuser verified in the layuser study.	No	S3P2	Risk II acceptable (benefit > risk)
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Use errors by layman	Confusion between result and control line test	Test is interpreted as negative whereas it is invalid - if the patient is in fact positive: patient not treated - no isolation measures taken, patient might infect other persons or Test is interpreted as invalid whereas it is negative - user needs another test	user error	S3P2	Control and test line region is highlighted on the cassette with letter C and T for control and test. In addition package insert shows device orientation relative to sample well. Correct handling of the device and understanding of the IFU by the layuser verified in the layuser study.	No	S3P1	Risk III acceptable

H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Use errors by layman	Modification of time for lecture: too long or too short	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	The reading time is present in the leaflet and on the kit. Correct handling of the device and understanding of the IFU by the layuser verified in the layuser study.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.2 H.2.4.4	Use errors by layman	Overlooking of faint test result line	False negative result: patient not treated - no isolation measures taken, patient might infect other persons	user error	S3P3	The information is given in the leaflet that the result should be considered positive whatever the intensity of the test line. Correct handling of the device and understanding of the IFU by the layuser verified in the layuser study.	No	S3P2	Risk II acceptable (benefit > risk)
H7 - Hazard related to using the test	H.2.2.3	Incorrect test interpretation	Interpretation error	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	Interpretation error	S3P2	The interpretation of the test is explained and illustrated in the leaflet. Correct handling of the device and understanding of the IFU by the layuser verified in the layuser study.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	H.2.2.3	Use errors by layman	storing reagent in inappropriate conditions	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	user error	S3P2	The recommended storage temperature is indicated on the kit and in the leaflet.	No	S3P1	Risk III acceptable
H7 - Hazard related to using the test	na	Use errors by layman	Incorrect extraction of the swab in the extraction buffer	False negative result: patient not treated - no isolation measures taken, patient might infect other persons	user error	S3P3	Detailed instructions in the leaflet. Availability of a video explaining the procedure.	No	S3P2	Risk II acceptable (benefit > risk)

Classification	NF EN ISO 14971:2012 Annex H	Hazardous situation Annexe H.2.5+G	Foreseeable hazard/ phenomene dangereux Annexe H.2.4	Possible effect (result)	Potential cause	Initial Risk level	Risk control measure CAPA	New hazard introduced ?	Residual Risk level	Residual risk acceptable?
H8 - Hazards of Failure of Performance	na	False results	False results	False negative result: patient not treated - no isolation measures taken, patient might infect other persons False positive result: patient inappropriately submitted to isolation measures	The nature/characteristic of the sample generates interference	S3P3	Study for testing potentially interfering substances, which showed that none of the tested substances interfered with the test	No	S3P1	Risk III acceptable
H8 - Hazards of Failure of Performance	na	False results	False results	False positive result: patient inappropriately submitted to isolation measures False negative result: patient not treated - no isolation measures taken, patient might infect other persons	Cross reaction with other interfering substances	S2P3	Cross reaction study which showed no cross reaction between test and tested pathogens. Information on relevant pathogens tested for cross reaction included in the IFU	No	S2P1	Risk III acceptable
H8 - Hazards of Failure of Performance	na	Poor quality of the specimen	Poor quality of the specimen	False positive result: patient inappropriately submitted to isolation measures Invalid result: user needs another test	Poor quality of the specimen	S3P2	Warning included in the IFU: specimen must not be used if overly viscous or if presence of blood visually noticed	No	S3P1	Risk III acceptable
H8 - Hazards of Failure of Performance	H2.4.3	Diagnostic sensitivity of the test	Inappropriate sensitivity of the test	False negative result: patient not treated - no isolation measures taken, patient might infect other persons	wrong performances	S3P2	Clinical accuracy study QC upon receipt Warning included in the IFU: the diagnosis must not be based only on the result of the rapid test, all clinical and laboratory findings must be taken into account by the physician	No	S3P1	Risk III acceptable
H8 - Hazards of Failure of Performance	H2.4.3	Analytical sensitivity of the test	Inappropriate sensitivity of the test	False negative result if antigen level in the speicmen is under the LoD: patient not treated - no isolation measures taken, patient might infect other persons False negative result: patient not treated - no isolation measures taken, patient might infect other persons	wrong performances	S3P3	Analytical sensitivity study Warning included in the IFU: the diagnosis must not be based only on the result of the rapid test, all clinical and laboratory findings must be taken into account by the physician	No	S3P2	Risk II acceptable (benefit > risk)
H8 - Hazards of Failure of Performance	H2.4.3	Product is not stable	Product is not stable	False positive result: patient inappropriately submitted to isolation measures Invalid result: user needs another test	inappropriate stability of the product	S3P3	Shelf life and stability determined in accelerated stability study. Real time stability study in process.	No	S3P2	Risk II acceptable (benefit > risk)
H8 - Hazards of Failure of Performance	na	Overly viscous sample	Migration problem	No migration / invalid test result: user needs another test	Nature of the sample	S3P2	Added instructions in IFU: if necessary let the patient blow their nose. The dropper nozzle of the extraction tube has a filter to filter out excess mucus	No	S3P1	Risk III acceptable

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H9 - QC Hazard	na	False results	False results	False results	Incorrect QC Samples used, inappropriate QC procedure	S2P2	Manufacturing & QC inspection documents; training procedures (QSP-2600)	No	S2P1	Risk III acceptable
H9 - QC Hazard	na	QC sample testing	assaying the wrong sample	delay in-production-may not meet customer needs	untrained personnel	S1P2	training and double checked by product quality	No	S1P1	Risk III acceptable
H9 - QC Hazard	na	QC sample testing	performing testing on unapproved device	testing will be need to be repeated-delay in production	untrained personnel	S1P2	training and incoming acceptance	No	S1P1	Risk III acceptable
H9 - QC Hazard	na	performing the assay in-house (i-process, QC, etc.)	using an unapproved device	may give wrong results, testing will need to be repeated-delay production	untrained personnel	S1P2	training and inspection of the device prior testing	No	S1P1	Risk III acceptable
H9 - QC Hazard	na	performing the assay in-house (i-process, QC, etc.)	incorrect volume of sample assayed	may give wrong results, testing will need to be repeated-delay production	untrained personnel	S1P2	training	No	S1P1	Risk III acceptable
H9 - QC Hazard	na	performing the assay in-house (i-process, QC, etc.)	incorrect volume of buffer used	may give wrong results, testing will need to be repeated-delay production	untrained personnel	S1P2	training	No	S1P1	Risk III acceptable
H9 - QC Hazard	na	performing the assay in-house (i-process, QC, etc.)	incorrect timing	may give wrong results, testing will need to be repeated-delay production	untrained personnel	S1P2	training/timer calibration verification	No	S1P1	Risk III acceptable
H9 - QC Hazard	na	performing the assay in-house (i-process, QC, etc.)	incorrect interpretation of results	may give wrong results, testing will need to be repeated-delay production	untrained personnel/faded color scale	S1P2	training/keep color scale stores out of light/expiry documented and new scales distributed prior to expiration.	No	S1P1	Risk III acceptable
H9 - QC Hazard	na	kit release testing	failed kit combination testing - false -/false +	lot not released	device and wash not compatible	S3P2	final kit QC testing	No	S3P1	Risk III acceptable
H9 - QC Hazard	na	kit release testing	Not operate in accordance with inspection procedure of final-product.	Failed products were used by patients.	personnel error	S3P2	Inspect strictly in accordance with inspection procedure of final-product. Inspection Procedure of Bath release is formalized.	No	S3P1	Risk III acceptable
H9 - QC Hazard	na	kit release testing	Batch to batch inconsistencies or batch homogeneity problem.	Failed products were used by patients.	production error	S3P2	Batch release certificate is established by the manufacturer. As the quality control is a destructive one it is logical that not all tests can be tested but only random samples can be taken.	No	S3P1	Risk III acceptable

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H10 - Reader Hazard	na	Software Hazard	inaccurate result	patient not treated	Wrong Adaptation of Biosynex Rapid test to BSX Reader.	S3P3	QC control of the programm Comparison study between visual reading and the BSX Reader	No	S3P2	Risk II acceptable
H10 - Reader Hazard	na	Software Hazard	Wrong programation of the method for the reading of the TDR on the BSX Reader	inaccurate result	Wrong Adaptation of Biosynex Rapid test to BSX Reader.	S3P3	Evaluation of the program during the development phase QC control	No	S3P2	Risk II acceptable
H10 - Reader Hazard	na	Software Hazard	Wrong programme selection by the user. The program doesn't correspond to the test	inaccurate result	user error	S3P3	The user is required to scan the QR code printed on the pouch of the rapid test in order to confirm the correspondance of the selected program to the used test	No	S3P1	Risk III acceptable
H10 - Reader Hazard	na	Software Hazard	Wrong QR code printed on the pouch of the rapid test	test cannot be used with the reader - not possible to generate results	Production error	S3P2	QC control of the rapid test in combination with the BSX Reader	No	S3P1	Risk III acceptable
H10 - Reader Hazard	na	Software Hazard	no cassette in the reader	inaccurate or invalid result	User error	S3P2	Alarm system: "cassette not found"	No	S3P1	Risk III acceptable
H10 - Reader Hazard	na	Software Hazard	Upside down cassette in the reader	inaccurate result	User error	S3P2	The shape of the drawer has been designed to avoid the misplacement of the cassette	No	S3P1	Risk III acceptable
H10 - Reader Hazard	na	Software Hazard	Reader out of order	no result	Perform a visual reading of the test.	S3P2	Warning in the IFU: the test must only be read with the BSX Reader	No	S3P1	Risk III acceptable
H10 - Reader Hazard	na	Software Hazard	The user tries to read the test with a different reader than the BSX Reader	inaccurate or invalid result	User error	S3P2	Warning in the IFU: the test must only be read with the BSX Reader. The BSX Reader and its reference is listed in the IFU as a material required but not supplied in the kit.	No	S3P1	Risk III acceptable
H10 - Reader Hazard	na	Software Hazard	The QR code printed on the pouch is damaged when the pouch is teared open.	The user cannot scan the QR code to confirm the selected program on the BSX Reader	user error	S3P4	The QR code sticker is in the middle of the pouch in order for the user to be able to open the pouch without tearing the sticker.	No	S3P2	Risk II acceptable
H10 - Reader Hazard	na	Software Hazard	The user discardes the pouch immediately after opening and before scanning the Qr code printed on the pouch	The user cannot scan the QR code to confirm the selected program on the BSX Reader	user error	S3P4	Warning in the IFU: the pouch must not be discarded	No	S3P3	Risk II acceptable
H10 - Reader Hazard	na	Software Hazard	The user does not know how to use the BSX Reader	Wrong procedure - obtained results are invalid or inaccurate	The user is not familiar with instructions for use of the BSX Reader	S3P3	Warning in the IFU: the user must read the user manual of the BSX Reader before starting the test	No	S3P1	Risk III acceptable

Classification	NF EN ISO 14971:2012 Annex H	Hazardous situation Annexe H.2.5+G	Foreseeable hazard/ phenomene dangereux Annexe H.2.4	Possible effect (result)	Potential cause	Initial Risk level	Risk control measure CAPA	New hazard introduced ?	Residual Risk level	Residual risk acceptable?
Regulatory affairs	na	Technical file	Technical documentation incomplete and not update : non-compliance with the market requirements : TDF, IFU, label, CE mark (CE mark not applicable yet for sel ftest version). Performance failure.	Regulatory affairs requirement not fullfilled	Human error	S2P1	Processes and SOP formalized	No	S2P1	Risk III acceptable
Regulatory affairs	na	Technical file	Non-existent supplier contracts.	Regulatory affairs requirement not fullfilled	Human error	S2P1	Processes and SOP formalized	No	S2P1	Risk III acceptable
Regulatory affairs	na	Technical file	Non-existent OBL client contracts.	Regulatory affairs requirement not fullfilled	Human error	S2P1	Processes and SOP formalized	No	S2P1	Risk III acceptable
Regulatory affairs	na	Notified body	Uninformed notified body of a major change.	Regulatory affairs requirement not fullfilled	Human error	S2P1	Processes and SOP formalized	No	S2P1	Risk III acceptable
Regulatory affairs	na	Competent authorities	Registration of the products at SwissMedic not carried out before they are placed on the market.	Regulatory affairs requirement not fullfilled	Human error	S2P1	Processes and SOP formalized	No	S2P1	Risk III acceptable
SMQ	na	Quality management system	The quality Management system is not controlled : non-current or unmanaged SOP, not internal auditing, problem of competency management.	QMS requirement not fullfilled	Human error	S2P1	Processes and SOP formalized	No	S2P1	Risk III acceptable
Customer order hazard	na	Shipping	Incorrect product shipped.	Delay in product receipt	Untrained personnel	S2P2	Training/double check by shipping	No	S2P1	Risk III acceptable
Customer order hazard	na	Shipping	Incorrect quantity/batch shipped.	Delay in product receipt traceability lost	Untrained personnel	S2P2	Training/double check by shipping	No	S2P1	Risk III acceptable
Customer order hazard	na	Shipping	Shipped to an incorrect address.	Delay in product receipt	Untrained personnel	S2P2	Training/double check by shipping	No	S2P1	Risk III acceptable
Vigilance	na	Complaint	Customer complaint reception and record.	Delay in recall	Human error	S2P2	Processes and SOP formalized	No	S2P1	Risk III acceptable
Vigilance	na	Non-conformity	Anomaly/Non-conformity detection and record.	Non-conform product on the market	Human error	S2P2	Processes and SOP formalized	No	S2P1	Risk III acceptable
Vigilance	na	Non-conformity	Investigate complaint/Anomaly/ non-conformity.	Non-conform product on the market	Human error	S2P2	Processes and SOP formalized	No	S2P1	Risk III acceptable
Vigilance	na	CAPA	Implement actions in order to correct anomaly/complaint.	Non-conform product on the market	Human error	S2P2	Processes and SOP formalized	No	S2P1	Risk III acceptable
Vigilance	na	Recall-vigilance	Product recall and vigilance.	Non-conform product on the market	Human error	S2P2	Processes and SOP formalized	No	S2P1	Risk III acceptable

Product: BIOSYNEX COVID-19 Ag / BIOSYNEX COVID-19 Ag BSX / BIOSYNEX AUTOTEST COVID-19 Ag
Ref: SW40006 / SW40006_BSX / 859256 / 859257 / 859258

HISTORY/REVIEW/CHANGES *Changes are highlited in green typo

Revision	Date	Sheet	Reason/Changes	Comment	Involved people
1	22/09/2020	All	Creation of the document	/	5.1.2e
2	03/11/2020	H10	Creation of the sheet H10 for the new variant SW40006_BSX which is intended to be used with the BSX READER (REF. 5080029)	/	
3	15/02/2021	H8; H7 user Pro	Addition of H8 line 8; H7 lines 16-18	/	
4	23/02/2021	H7 User layman	Creation of the tab for laymen users	/	