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Lieferung & Zahlungsart

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Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

SZABO-SCANDIC HandelsgmbH

Quellenstraße 110, A-1100 Wien



T. +43(0)1 489 3961-0

F. +43(0)1 489 3961-7

mail@szabo-scandic.com

www.szabo-scandic.com

[linkedin.com/company/szaboscandic](https://www.linkedin.com/company/szaboscandic)

EN	REF 1N1900	Lyophilized PCR mix for DNA amplification in Real Time PCR	IVD
	STAT-NAT® SN200 DNA Mix	REAGENT: 6 x Master Mix miniplate	 96 
NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.			

INTENDED USE

The STAT-NAT® SN200 DNA Mix is a master mix for automated nucleic acid amplification of DNA samples extracted from human specimens¹.

The kit can be used for assay based on Real-time PCR and performed on an automated extraction and nucleic acid amplification system. The kit is intended to be used in combination with primers and probes for in vitro diagnostic procedures. For professional use only.

PRINCIPLE

STAT-NAT® SN200 DNA Mix kit is a versatile PCR mix necessary to perform a Real-Time PCR reaction based on SENTINEL CH. S.p.A. proprietary freeze-dried amplification reagents that guarantee the sensitivity and the specificity of the reaction without intermediate manual steps for setting up reaction mixtures. The kit consists of 6 miniplates, each containing 16 optimized freeze-dried master mixes (96 reactions total).

The STAT-NAT® SN200 DNA Mix is intended to be used with pre-optimized primers and probes, such as the STAT-NAT® SN200 oligonucleotides (Oligo) assays.

The combination of DNA mix and oligo assay is validated on the SENTiNAT® 200 automated system and self-contained assay-specific STAT-NAT® SN200 Plugin, in conjunction with the STAT-NAT® SN200 Controls kit, the STAT-NAT® SN200 Calibrator kit and a dedicated DNA extraction kit.

REAGENTS

STAT-NAT® SN200 DNA Mix kit consists of:

- REAGENT: 6 miniplates x 16 master mix wells

The kit includes 6 aluminum pouches labelled *Master Mix miniplate*, containing a single miniplate with 16 lyophilized Master Mixes and a small orange desiccant sachet.

Each PCR well contains:

- dNTPs (dATP, dCTP, dGTP and dTTP);
- Hot Start (Taq) Polymerase;
- Reaction buffer.

Lyophilized Master Mix must be stored at +15/+30 °C. Use only undamaged packages.

On board miniplate stability: stable up to 7 days if placed on the specific miniplate carriers and loaded on SENTiNAT® 200 automated system.

The kit components are barcoded to be automatically read by SENTiNAT® 200 automated system.

INSTRUMENTATION AND MATERIALS REQUIRED BUT NOT PROVIDED

Oligo assay kits: homemade primers and probes mixes or Oligo kits available at the market, such as STAT-NAT® SN200 oligo assays.

Positive controls kit: homemade controls or control kits available at the market, such as STAT-NAT® SN200 Controls for oligo assays.

Calibrator kit: homemade calibrators or calibrator kits available at the market, such as STAT-NAT® SN200 Calibrators for oligo assays.

Consumables/Accessories: Hamilton MIC Tubes & V-Caps – REF DS0009, SENTiNAT® 200 extraction kit consumable set – REF.1N1004, Elution plates – REF. 1N1008 and Deep Well Plate – REF. DS0005.

General molecular laboratory equipment: biosafety cabinet (laminar flow hood) for samples handling, centrifuge/micro-centrifuge, vortex mixer, variable volume pipettes, sterile disposable plastics.

Extraction Kit: SENTiNAT® X48 Pathomag Extraction kit – REF. 1N1009.

Personal protective equipment (PPE): as gloves, laboratory coats, safety glasses, facemasks.

Validated automated system: SENTiNAT® 200, and the dedicated instrument consumables.

Software platform and Analysis Software: FastFinder (UgenTec), the assay-specific STAT-NAT® SN200 Plugin related to the Oligo assays. The analysis software can be supplied on request. Fill out the online request form on <https://www.ugentec.com/create-account> to set up your account.

CAUTION: Refer to FastFinder (UgenTec) website to ensure you are using the most current version of the analysis software.

WARNINGS AND PRECAUTIONS

- The STAT-NAT® SN200 DNA Mix kit – REF. 1N1900 is intended to be used in combination with primers and probes for in vitro diagnostic procedures;

-Read all the instructions contained in the kit insert before performing the test;

-Comply with the kit expiration date;

-Do not mix up reagents for amplification or consumables from other commercial kits;

-Do not mix up reagents or consumables from kits with different Lot Number;

-Do not use any reagents if the safety seal is broken or if the packaging is damaged upon arrival;

-Do not use consumables or reagents if the protective pouch is open or broken upon arrival;

-The MSDS are available at www.sentinel diagnostics.com or at your local supplier;

-Keep all miniplates, with lyophilized Master Mix, protected from light and humidity in their aluminum envelopes;

-Avoid microbial, ribonuclease (RNase) and deoxyribonuclease (DNase) contamination of all reagents and consumables;

-In cases where open-tube PCR tests are also conducted by the laboratory, care must be taken to ensure that the consumables and reagents required for testing, personal protective equipment such as gloves and lab coats, and the SENTiNAT® 200 System are not contaminated;

-Wash hands thoroughly after performing the test;

-Do not pipette by mouth. Do not smoke, drink, or eat in areas where specimens or reagents are being handled.

-Always use personal protective equipment for the individual protection;

-The product must be handled by staff trained in molecular biology techniques, such as nucleic acids extraction, amplification, detection and in automation;

-CAUTION This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens², Biosafety Level 2³ or other appropriate biosafety practices^{4,5} should be used for materials that contain or are suspected of containing infectious agents.

INSTRUCTIONS FOR USE

Miniplates highlights:

1. Ensure that before using pouches, they are always well sealed and that the desiccant sachets are still inside. Use only undamaged packages;
2. Cut the aluminum pouches at the point indicated by the lateral notches;
3. Remove the miniplates from the pouches immediately before use;
4. Examine the lyophilized Master Mix before use to verify that the content has a solid and white appearance. Please discard the product that appears with signs of moisture contamination (i.e. change of colour, collapsing product, etc...);
5. Make sure Lyophilized Master Mix is at the bottom of the test well before to load the miniplates into the specific carriers;
6. Waste the aluminum pouches and their content if the desiccant sachets turn from orange to green.
7. All reagents, correctly stored at +15/+30 °C, are stable up to the expiration date indicated on the package;

Warning: Do not remove the aluminum foil from the miniplates top. Do not shake or invert the miniplates.

For a detailed description of how to load the STAT-NAT® SN200 DNA Mix kit miniplate on the SENTiNAT® 200 system, refer to the SENTiNAT® 200 Operator's Manual.

PROCEDURE

SENTiNAT® 200 application and sample-to-result run

1. The STAT-NAT® SN200 DNA Mix kit can process a maximum of 48 samples per run;
2. For the required minimum sample volume, refer to the specific Oligo assay;
3. Refer to the SENTiNAT® 200 Operator's Manual for acceptable tube size and appropriate sample rack type;
4. For a detailed description of how to operate the SENTiNAT® 200 system, refer to the SENTiNAT® 200 Operator's Manual.

TROUBLESHOOTING












- Refer to the troubleshooting section in the Oligo assays Instruction For Use;
- For the SENTiNAT® 200 instrument please refer to manual troubleshooting

WASTE MANAGEMENT

- The reagents of the kit are not classified as dangerous according to Regulation EC 1272/2008 (CLP). Adopt good working practices, so that the product is not released into the environment. Recover if possible. In so doing, comply with the local and national regulations currently in force.
- Manage and waste all the biological samples as potentially infectious. All the material that come in contact with the biological sample must be treated with 0.5% sodium hypochlorite for at least 30 minutes or sterilized in autoclave at 121 °C for 30 minutes and then wasted.

BIBLIOGRAPHY

- 1) Mullis KB, Faloona FA. Specific synthesis of DNA in vitro via a polymerase-catalyzed chain reaction. *Methods Enzymol.*1987;155:335-50
- 2) US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. Bloodborne Pathogens. <https://www.osha.gov/lawsregs/regulations/standardnumber/1910/1910.1030>
- 3) US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories, 5th Ed. Washington,DC: US Government Printing Office, December 2009.
- 4) World Health Organization. Laboratory Biosafety Manual, 3rd ed. Geneva: World Health Organization, 2004.
- 5) CLSI. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline — Fourth Edition (M29-A4). Clinical and Laboratory Standards Institute, 2014.

Explanation of symbols			EN
REAGENT / CONTROL The terms refer to the: single reagent/control			
 In vitro Diagnostic Medical Device	 Catalogue number	 Batch code	
 Contents of kit	 Contains sufficient for <n> tests	 Manufacturer	
 Caution, consult accompanying documents. Consult instructions for use		 Temperature limitation	
 Protect from humidity	 Do not expose the reagent to the light	 Use by	

STAT-NAT® and SENTiNAT® are a trademark in various jurisdictions which is exclusively licensed to SENTINEL CH. SpA.

Note: changes in comparison to the previous version are indicated by a vertical bar in the text margin

In case of incident, please contact Sentinel Diagnostics (contact details at www.sentinel diagnostics.com) or your local representative.

For customers in the European Union: if, in the course of using this device, you have reason to believe that a serious incident has occurred, report it to the manufacturer and to your national authority.