

SAFETY DATA SHEET

Release Date: 10-07-2020, revision 1.0

SECTION 1: Identification

Product Identifier	800600 NeuMoDx BKV Calibrator
Synonyms	2NX12C NeuMoDX_BKV Calibrator Set 2NX01B NeuMoDX_BKV Calibrator Buffer
Relevant Identified Use	For <i>in vitro</i> diagnostic use
Manufacturer	SENTINEL D I A G N O S T I C S SENTINEL CH. SpA Via Robert Koch, 2 20152 Milan - Italy www.sentinel diagnostics.it
Telephone	(+39 02 3455 141
Distributor	QIAGEN GmbH QIAGEN Str. 1 40724 Hilden Germany Technical Support: 00800-22-44-6000 www.qiagen.com/support
Emergency Telephone Number	(+39 02 3455 1495
Technical Support: Relevant Identified Use	customerservice@sentinel.it For <i>in vitro</i> diagnostic use

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

Globally Harmonized System (GHS)	This mixture does not meet criteria for classification under GHS as implemented by Regulation EC No 1272/2008 (EU CLP). It has not been fully tested and should be handled with caution.
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2.2 Label Elements

GHS Hazard Pictogram	None required
GHS Signal Word	None required
GHS Hazard Statements	None required

Other Hazards	Hazards not otherwise classified (HNOC) or not covered by GHS are unknown. This mixture contains material derived from human plasma and should be treated as a potential biological hazard. All such material has been shown by FDA approved methods to be free from antibodies to Human Immunodeficiency Virus and Hepatitis C and is non-reactive for HBsAg, anti-HIV-1/2, anti-EBV, anti-HTLV I/II, anti-HBs, and anti-HBc.
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- 2.3 Other information This mixture does not meet criteria for classification under GHS as implemented by Regulation EC 1272/2008 (EU CLP).

SECTION 3: Composition/Information on Hazardous Ingredients

Mixtures Mixture of chemical and/or biological substances for *in vitro* diagnostic use

Hazardous chemical ingredients per Regulation EC No 1272/2008 (EU CLP)				
Ingredient	CAS #	EINECS/ELINCS#	Concentration	GHS Classification
N/A	N/A	N/A	N/A	N/A

SECTION 4: First Aid Measures

- 4.1 Description of first aid measures
- | | |
|------------------------------------|--|
| Immediate medical attention needed | No |
| General Advice | Get medical attention. Show this safety data sheet to doctor in attendance. |
| After inhalation | First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Move exposed personnel to fresh air. Administer oxygen if breathing is difficult. Keep patient warm. Consult doctor if symptoms persist. |
| After skin contact | First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Take off any clothing that the product touched. Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur. |
| After eye contact | First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. If eye irritation persists, seek medical attention. |
| After swallowing | First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention. |
- 4.2 Most important symptoms and effects, acute and delayed See Sections 2 and 11
- 4.3 Indication of any immediate medical attention and special treatment needed Notes for the doctor: All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

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SECTION 5: Fire-Fighting Measures

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| 5.1 | Extinguishing media | |
| | Suitable extinguishing media | Use alcohol resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers. |
| | Unsuitable extinguishing media | Unknown |
| 5.2 | Special hazards arising from the substance or mixture | None identified. May emit oxides of nitrogen, carbon monoxide and carbon dioxide. |
| 5.3 | Advice for firefighters | As in any fire, wear self-contained breathing apparatus pressure demand (NIOSH-approved or equivalent) and full protective gear to prevent contact with skin and eyes. |

SECTION 6: Accidental Release Measures

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| 6.1 | Personal precautions, protective equipment and emergency procedures | If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). |
| 6.2 | Environmental precautions | Avoid release to the environment. |
| 6.3 | Methods and materials for containment and cleaning | Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations. |

SECTION 7: Handling and Storage

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| 7.1 | Precautions for safe handling | Ensure good ventilation in the workplace. |
| 7.2 | Conditions for safe storage | Store frozen. See product instructions for use for specific recommended storage conditions. |

SECTION 8: Exposure Controls/Personal Protection

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| 8.1 | Occupational exposure limits | No data available. |
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| 8.2 | Engineering measures | Ensure adequate ventilation, especially in confined areas. Handle in accordance with good industrial hygiene and safety practices. Wash hands before breaks and at the end of the workday. |
| 8.3 | Personal protective equipment (PPE) | Personal protective equipment requirements are dependent on the user institution's risk assessment and are specific to the risk assessment for each laboratory where this material may be used. |
| | Respiratory protection | Choice of respiratory protection is dependent on the user institution's risk assessment. |
| | Hand protection | Impervious gloves |
| | Eye protection | Safety glasses with side shields |
| | Skin and body protection | Lab coat over lightweight, protective clothing |
| | Hygiene measures | Handle in accordance with good industrial hygiene and safety practices. |
| 8.4 | Environmental exposure controls | No special environmental precautions required |

SECTION 9: Physical and Chemical Properties

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| 9.1 | General Information | |
| | Physical State | 2NX12C Solid (dried-down)
2NX01B Liquid |
| | Color | 2NX12C White
2NX01B Colorless |
| | Odor | Odorless |
| | Odor threshold | Not determined |
| | pH value at 20°C (68°F) | 7.0-8.0 |
| | Melting point/melting range | Not determined |
| | Boiling point/boiling range | Not determined |
| | Freezing point | Not determined |
| | Flash point | Not determined |
| | Flammability (solid, gaseous) | Not applicable |
| | Auto igniting | Product is not self-igniting |
| | Danger of explosion | Product does not present an explosion hazard |
| | Explosion limits: | |
| | Lower | Not determined |
| | Upper | Not determined |
| | Density at 20°C | Not determined |
| | Vapor pressure | Not determined |
| | Relative vapor density | Not determined |
| | Particle characteristics | Not determined |
| | Partition coefficient (n-octanol/water) | Not determined |
| | Decomposition temperature | Not determined |

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Kinematic viscosity	Not determined
Solubility in/miscibility with:	
Water	Miscible
Dynamic	Not determined

9.2 Other information No additional physical and chemical parameters noted

SECTION 10: Stability and Reactivity

Reactivity	Sodium azide may react with lead or copper plumbing to form explosive metal azides.
Chemical stability	Stable when stored as recommended.
Possibility of hazardous reactions	No data available.
Conditions to avoid	No data available.
Incompatible materials	No data available.
Hazardous decomposition products	No data available.

SECTION 11: Toxicological Information

Information on toxicological effects

Acute toxicity	No data available
Skin corrosion/irritation	No data available
Serious eye damage/eye irradiation	No data available
Respiratory or skin sensitization	No data available
Ingestion	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	No data available
Reproductive toxicology	No data available
Specific target organ toxicity-single exposure	No data available

SECTION 12: Ecological Information

Ecotoxicity Effects	No information available
Acute Aquatic Toxicity	No information available
Chronic Aquatic Toxicity	No information available
Mobility in Soil	No information available
Biodegradation	No information available
Bioaccumulation	Does not bioaccumulate

SECTION 13: Disposal Considerations

Waste Treatment Methods
Dispose of in accordance with local regulations in a segregated manner. See Section 6, above.

SECTION 14: Transport Information

Proper shipping name Not classified as dangerous to transport

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UN N°	None
Transport hazard class(es)	None
Subsidiary class	None
Packing group	None

SECTION 15: Regulatory Information

This SDS generally complies with current guidelines in the EU. Consult local authorities for more information.

Europe

Candidate substances for authorization under the Regulation (EC) No 1907/2006 (REACH)

Not applicable.

Substances included in Annex XIV of REACH ("Authorization List") and sunset date

Not applicable.

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer

Not applicable.

Article 95, Regulation (EU) No 528/2012

Not applicable.

Regulation (EU) No 649/2012, in relation to the import and export of hazardous chemical products

Not applicable.

Limitations to commercialization and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc.)

Not applicable.

SECTION 16: Other Information

Disclaimer/Statement of Liability

The Safety Data Sheet (SDS) contains all information as required by the Hazard Communication Standard and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. The responsibility to provide a safe workplace remains with the user who should consider the health hazards and safety information contained in this document as a guide. The user should take the precautions required. Caution should be used in the handling and use of the material. No representation, warranty, or guarantee, express or implied, including a warranty of fitness or merchantability for a particular purpose is constituted by the information in this SDS.