**INTENDED USE**
The NeuMoDx™ Lysis Buffer 4 is a proprietary lysis and binding buffer that when used in conjunction with NeuMoDx™ supplied consumables, NeuMoDx™ Extraction Plate, NeuMoDx™ Wash Reagent, and NeuMoDx™ Release Reagent, enables the extraction of DNA from Gram-positive bacteria from clinical samples on the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System[s]).

**SUMMARY AND EXPLANATION**
NeuMoDx Lysis Buffer 4 is supplied in a disposable container, which includes at least 80 mL of usable buffer. NeuMoDx Lysis Buffer 4 contains a proprietary formulation of detergent and buffering agents to provide efficient lysis of Gram-positive bacteria in clinical samples.

Use of this buffer to extract nucleic acid from specimens other than enriched Lim broth or for bacteria other than group B Streptococcus (GBS) has not been validated.

**PRINCIPLES OF THE PROCEDURE**
The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of enriched Lim Broth is mixed with NeuMoDx Lysis Buffer 4 and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres dried in the NeuMoDx Extraction Plate.

The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx Wash Reagent and the bound nucleic acid is eluted using NeuMoDx Release Reagent.

The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx™ test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.

**REAGENTS / CONSUMABLES**

**Material Provided**

<table>
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<tr>
<th>REF</th>
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<th>Tests per unit</th>
<th>Tests per package</th>
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<tr>
<td>400700</td>
<td>NeuMoDx™ Lysis Buffer 4</td>
<td>~ 80*</td>
<td>~ 560*</td>
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* tests per unit/package may vary depending on actual use

**NeuMoDx™ Reagents and Consumables Required But Not Provided**

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<tr>
<td>100200</td>
<td>NeuMoDx™ Extraction Plate Dried magnetic affinity microspheres, lytic enzymes, and sample process controls</td>
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<td>400100</td>
<td>NeuMoDx™ Wash Reagent</td>
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<tr>
<td>400200</td>
<td>NeuMoDx™ Release Reagent</td>
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<tr>
<td>100100</td>
<td>NeuMoDx™ Cartridge</td>
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<tr>
<td>various</td>
<td>NeuMoDx™ test Strip (as applicable)</td>
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<tr>
<td>235903</td>
<td>Hamilton CO-RE Tips (300 µL) with Filters (available from NeuMoDx or Hamilton)</td>
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<tr>
<td>235905</td>
<td>Hamilton CO-RE Tips (1000 µL) with Filters (available from NeuMoDx or Hamilton)</td>
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**Other Equipment and Materials Required But Not Provided**

NeuMoDx™ 288 Molecular System [REF 500100] OR NeuMoDx™ 96 Molecular System [REF 500200]
WARNINGS & PRECAUTIONS

- This reagent is for in vitro diagnostic use with NeuMoDx Systems only.
- Do not refrigerate.
- Do not use any reagents after the listed expiration date.
- Do not use if the safety seal is broken or if the packaging is damaged upon arrival.
- Do not use if foil seal is damaged upon arrival or if signs of leakage are present.
- Be sure to remove the foil seal from the container prior to loading NeuMoDx Lysis Buffer 4 into the carrier for use.
- Ensure that NeuMoDx Buffer 4 is at room temperature before use on the NeuMoDx System.
- Do not reuse any NeuMoDx consumable or reagent.
- Safety Data Sheets (SDS) are provided for each reagent.
- Always wear clean powder free nitrile gloves when handling specimens or any NeuMoDx reagents or consumables.
- Wash hands thoroughly after performing the test.
- Do not pipette by mouth. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Always handle specimens as if they are infectious and in accordance with safe laboratory procedures such as those described in *Biosafety in Microbiological and Biomedical Laboratories* ¹ and in CLSI Document M29-A4 ².
- Dispose of unused reagents and waste in accordance with country, federal, provincial, state and local regulations.

PRODUCT STORAGE, HANDLING & STABILITY

- NeuMoDx Lysis Buffer 4 is stable in the primary packaging at 18 to 28 °C through the stated expiration date on the immediate product label.
- Do not refrigerate.
- Do not use reagents past the stated expiration date.
- Do not use if product or packaging has been visually compromised. The presence of some minor precipitation after removal of the foil seal is normal; this will not prevent successful use of NeuMoDx Lysis Buffer 4 on the NeuMoDx System.
- NeuMoDx Buffer 4 containers placed on the worktable of the NeuMoDx System are stable for 28 days when operating within the environmental conditions specified in the *NeuMoDx™ 288/96 Molecular System Operator’s Manual(s)*. The NeuMoDx System software will prompt the removal of buffer containers that have been in-use on the NeuMoDx System for longer than 28 days.

SPECIMEN COLLECTION, TRANSPORT & STORAGE

Validation of optimal Specimen Shipping Conditions and Specimen Stability should be conducted by the user’s laboratory for the sample matrix used for each type of test performed.

INSTRUCTIONS FOR USE

1. Ensure that NeuMoDx Lysis Buffer 4 is at Room temperature before use on the NeuMoDx System. Invert the container several times to mix the buffer before removal of the foil seal.
2. **IMPORTANT** Prepare NeuMoDx Lysis Buffer 4 container for use by pulling on the tab of the foil seal to remove it.
3. Some residual buffer on top of the septum cover is expected after removal of the foil seal; this will not impact performance. If buffer is noticeable on either side of the container, dab the sides gently using a low lint tissue such as a Kimwipe® to absorb prior to placing in the Buffer Carrier. Do not touch anything to the top surface of the septum cover.
4. To ensure proper orientation when positioning the container in the Buffer Carrier, the barcode should face to the right to be read by the barcode scanner.
5. Place the container with foil seal removed in the Buffer Carrier until it “snaps” into place.
6. Load the Buffer Carrier by touching the arrow below the Buffer Container icon on the NeuMoDx System touchscreen.
7. Upon successful loading of the Buffer Carrier, the NeuMoDx System software should recognize the type of buffer as “Lysis Buffer 4” and the Quantity as “80 mL”.
   a. If the Buffer Carrier is loaded correctly, but the NeuMoDx System software recognizes it as an EMPTY POSITION, ensure that the NeuMoDx Lysis Buffer 4 container is loaded in the proper orientation and the barcode is visible to the barcode scanner.
   b. If the Buffer Carrier is loaded correctly, but the NeuMoDx System software does not recognize it as “Lysis Buffer 4”, check to confirm that this is a NeuMoDx Lysis Buffer 4 container.
   c. If the Buffer Carrier is loaded correctly, and the NeuMoDx System software recognizes it as “Lysis Buffer 4”, but the quantity is not reported as “80 mL”, check to confirm that this is a NEW NeuMoDx Lysis Buffer 4 container.
LIMITATIONS

1. NeuMoDx Lysis Buffer 4 can only be used on the NeuMoDx System and is not compatible with any other automated molecular diagnostic system.

2. The performance of NeuMoDx Lysis Buffer 4 has only been validated using the NeuMoDx™ GBS Test Strip. The performance characteristics of user assays using this reagent is unknown and must be validated by the user’s laboratory before diagnostic claims can be made.

3. Because detection of most pathogens is dependent on the number of organisms present in the sample, reliable results are dependent on proper specimen collection, handling, and storage.

4. Erroneous test results could occur from improper specimen collection, handling, storage, technical error or sample mix-up. In addition, false negative results could occur because the number of organisms in the specimen is below the analytical sensitivity of the test.

5. Use of this reagent is limited to personnel trained on the use of the NeuMoDx System.

6. Good laboratory practices, including changing gloves between handling patient specimens, are recommended to avoid contamination of specimens.

REFERENCES


TRADEMARKS

NeuMoDx™ is a trademark of NeuMoDx Molecular, Inc.

TaqMan® is a registered trademark of Roche Molecular Systems, Inc.

Kimwipe® is a registered trademark of Kimberly-Clark Worldwide, Inc.
### SYMBOLS

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Ann Arbor, MI 48108, USA

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Patent: [www.neumodx.com/patents](http://www.neumodx.com/patents)

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