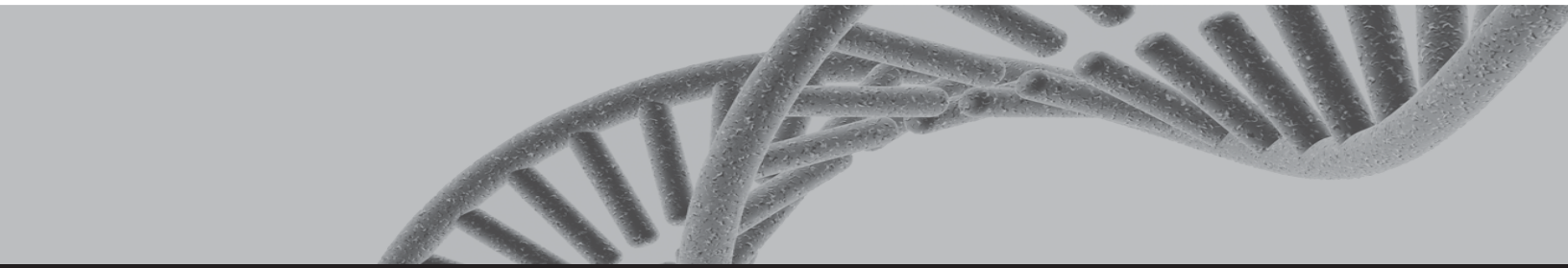
3M

Product Instructions
MDMC96

- (EN) Molecular Detection Matrix Control
- (FR) Contrôle de matrice pour système de détection moléculaire (France)
- (FR) Témoin matriciel pour analyse par détection moléculaire (Canada)
- (DE) Molekulare Detektion - Matrixkontrolle
- (IT) Controllo della matrice per il sistema di rilevazione molecolare
- (ES) Control de Matriz para Detección Molecular
- (NL) Moleculaire Detectie - Matrix controle
- (SV) Molekylär Detektion Matris Kontroll
- (DA) Molekylær Detektions Matrix Kontrol
- (NO) Matrisekontroll for molekylær detektering
- (FI) Molekyläärisen tunnistuksen Matrix Control
- (PT) Controle de Matriz para Detecção Molecular
- (EL) Πίνακας Ελέγχου Μοριακής Ανίχνευσης
- (PL) Kontrola macierzy do diagnostyki molekularnej
- (RU) Контроль матрицы для молекулярной диагностики
- (TR) Moleküler Tayin Matris Kontrolü
- (KK) Молекулярлық диагностикасы— матрицаны бақылау құралы
- (JA) 病原菌検出マトリックスコントロール
- (ZH) 分子检测样品对照 (Simplified)
- (ZH) 檢體基質抑制反應控制套組 (Traditional)
- (TH) ชุดน้ำยาควบคุมเพื่อทดสอบผลของส่วนประกอบในตัวอย่างแต่ละประเภท
- (KO) 분자 검출 매트릭스 컨트롤
- (ID) Kontrol Matriks Deteksi Molekuler



Matrix Control

Molecular Detection Matrix Control

Product Description and Intended Use

3M™ Molecular Detection Matrix Control is intended for use with the 3M™ Molecular Detection Assays and the 3M™ Molecular Detection System for the rapid and specific detection of selected pathogens in enriched food, feed and food process environmental samples. Presumptive positive results should be confirmed using your preferred method or as specified by local regulations.

The 3M Molecular Detection Matrix Control uses loop-mediated isothermal amplification to rapidly amplify nucleic acid sequences with high specificity and sensitivity, combined with bioluminescence to detect the amplification. Valid 3M Molecular Detection Matrix Control Assay results are reported in real-time while inhibited results will be displayed after the assay is completed.

It is generally accepted that sample matrix may interfere with any test method. To help customers evaluate the method for various food matrices, 3M has developed the 3M Molecular Detection Matrix Control kit. When needed, use the 3M Molecular Detection Matrix Control to determine if the matrix has the ability to impact the 3M Molecular Detection Assay results. Test several samples, representative of the matrix, i.e. samples obtained from different origin, during any validation period when adopting the 3M method or when testing new or unknown matrices or matrices that have undergone raw material or process changes.

A matrix can be defined as a type of product with intrinsic properties such as composition and process. Differences between matrices may be as simple as the effects caused by differences in their processing or presentation for example, raw versus pasteurized; fresh versus dried, etc.

The 3M Molecular Detection Matrix Control is intended for use in a laboratory environment by professionals trained in laboratory techniques. 3M has not documented the use of this product in industries other than food or beverage. For example, 3M has not documented this product for testing water, pharmaceutical, cosmetics, clinical or veterinary samples. The 3M Molecular Detection Matrix Control has not been evaluated with all possible food products, food processes, testing protocols or with all possible strains of bacteria.

As with all test methods, the source of enrichment medium can influence the results. 3M Molecular Detection Assays have have only been evaluated for use with the enrichment media specified in the **Instructions for Use** section of the assay Product Instructions.

The 3M™ Molecular Detection Instrument is intended for use with samples that have undergone heat treatment during the assay lysis step, which is designed to destroy organisms present in the sample. Samples that have not been properly heat treated during the assay lysis step may be considered a potential biohazard and should NOT be inserted into the 3M Molecular Detection Instrument.

3M Food Safety is certified to International Standards Organization (ISO) 9001 for design and manufacturing.

3M Molecular Detection Matrix Control contains 96 tests described in Table 1.

Table 1. Kit components

Item	Identification	Quantity	Contents	Comments
3M™ Molecular Detection Matrix Control (MC) Reagent Tubes	Clear	96 (12 strips of 8 caps)	Lyophilized DNA fragment, specific amplification and detection mix	Ready to use
Extra caps	Clear caps	96 (12 strips of 8 caps)		Ready to use
Quick Start Guide		1		

Safety

The user should read, understand and follow all safety information in the instructions for the 3M Molecular Detection System and the 3M Molecular Detection Matrix Control. Retain the safety instructions for future reference.

⚠**WARNING:** Indicates a hazardous situation, which, if not avoided, could result in death or serious injury and/or property damage.

NOTICE: Indicates a potentially hazardous situation which, if not avoided, could result in property damage.

⚠ WARNING

Do not use the 3M Molecular Detection Matrix Control in the diagnosis of conditions in humans or animals.
The user must train its personnel in current proper testing techniques: for example, Good Laboratory Practices, ISO/IEC 17025[1], or ISO 7218[2].

To reduce the risks associated with a false-negative result leading to the release of contaminated product:

- Follow the protocol and perform the tests exactly as stated in the product instructions.
- Store the 3M Molecular Detection Matrix Control as indicated on the package and in the product instructions.
- Always use the 3M Molecular Detection Matrix Control by the expiration date.
- Use the 3M Molecular Detection Matrix Control with food, feed and food process environmental samples that have been validated internally or by a third party.
- Use the 3M Molecular Detection Matrix Control only with surfaces, sanitizers, protocols and bacterial strains that have been validated internally or by a third party.
- For an environmental sample containing neutralizing buffer with aryl sulfonate complex, perform a 1:2 dilution before testing (1 part sample into 1 part sterile enrichment broth). Another option is to transfer 10 µL of the neutralizing buffer enrichment into the 3M™ Lysis Solution tubes. 3M™ Sample Handling Products which include neutralizing buffer with aryl sulfonate complex: BPPFV10NB, RS96010NB, RS9604NB, SSL10NB, XSLSSL10NB, HS10NB and HS119510NB.

To reduce the risks associated with exposure to chemicals and biohazards and to reduce risk associated with environmental contamination:

- Perform pathogen testing in a properly equipped laboratory under the control of trained personnel. Incubated enrichment media and equipment or surfaces that have come into contact with incubated enrichment media may contain pathogens at levels sufficient to cause risk to human health.
- Always follow standard laboratory safety practices, including wearing appropriate protective apparel and eye protection while handling reagents and contaminated samples.
- Avoid contact with the contents of the enrichment media, lysis tubes and reagent tubes after amplification.
- Dispose of enriched samples according to current local/regional/national/industry standards.
- Samples that have not been properly heat treated during the assay lysis step may be considered a potential biohazard and should NOT be inserted into the 3M Molecular Detection Instrument.
- Follow current industry standards for disposal of contaminated waste.

To reduce the risks associated with cross-contamination while preparing the assay:

- Always wear gloves (to protect the user and prevent introduction of nucleases).

To reduce the risks associated with exposure to hot liquids:

- Do not exceed the recommended temperature setting on heater.
- Do not exceed the recommended heating time.
- Use an appropriate, calibrated thermometer to verify the 3M™ Molecular Detection Heat Block Insert temperature (e.g., a partial immersion thermometer or digital thermocouple thermometer, not a total immersion thermometer). The thermometer must be placed in the designated location in the 3M Molecular Detection Heat Block Insert.

NOTICE

To reduce the risks associated with cross-contamination while preparing the assay:

- Change gloves prior to reagent pellet hydration.
- Use of sterile, aerosol barrier (filtered), molecular biology grade pipette tips is recommended.
- Use a new pipette tip for each sample transfer.
- Use Good Laboratory Practices to transfer the sample from the enrichment to the lysis tube. To avoid pipettor contamination, the user may choose to add an intermediate transfer step. For example, the user can transfer each enriched sample into a sterile tube.
- Use a molecular biology workstation containing germicidal lamp where available.

- Periodically decontaminate laboratory benches and equipment (pipettes, cap/decap tools, etc.) with a 1-5% (v:v in water) household bleach solution or DNA removal solution.

To reduce the risks associated with a false-positive result:

- Never open reagent tubes post amplification.
- Always dispose of the contaminated tubes by soaking in a 1-5% (v:v in water) household bleach solution for 1 hour and away from the assay preparation area.
- Never autoclave reagent tubes post amplification.

Consult the Safety Data Sheet for additional information and local regulations for disposal.

If you have questions about specific applications or procedures, please visit our website at www.3M.com/foodsafety or contact your local 3M representative or distributor.

User Responsibility

Users are responsible for familiarizing themselves with product instructions and information. Visit our website at **www.3M.com/foodsafety**, or contact your local 3M representative or distributor for more information.

When selecting a test method, it is important to recognize that external factors such as sampling methods, testing protocols, sample preparation, handling, laboratory technique and the product itself may influence results.

It is the user's responsibility in selecting any test method or product to evaluate a sufficient number of samples with the appropriate matrices and microbial challenges to satisfy the user that the chosen test method meets the user's criteria.

It is also the user's responsibility to determine that any test methods and results meet its customers' and suppliers' requirements.

As with any test method, results obtained from use of any 3M Food Safety product do not constitute a guarantee of the quality of the matrices or processes tested.

Limitation of Warranties / Limited Remedy

EXCEPT AS EXPRESSLY STATED IN A LIMITED WARRANTY SECTION OF INDIVIDUAL PRODUCT PACKAGING, 3M DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE. If any 3M Food Safety Product is defective, 3M or its authorized distributor will, at its option, replace or refund the purchase price of the product. These are your exclusive remedies. You must promptly notify 3M within sixty days of discovery of any suspected defects in a product and return it to 3M. Please call Customer Service (1-800-328-1617 in the U.S.) or your official 3M Food Safety representative for a Returned Goods Authorization.

Limitation of 3M Liability

3M WILL NOT BE LIABLE FOR ANY LOSS OR DAMAGES, WHETHER DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS. In no event shall 3M's liability under any legal theory exceed the purchase price of the product alleged to be defective.

Storage and Disposal

Store the 3M Molecular Detection Matrix Control at 2-8°C. Do not freeze. Keep kit away from light during storage. After opening the kit, check that the foil pouch is undamaged. If the pouch is damaged, do not use. After opening, unused reagent tubes should always be stored in the re-sealable pouch with the desiccant inside to maintain stability of the lyophilized reagents. Store resealed pouches at 2-8°C for no longer than 60 days.

Do not use 3M Molecular Detection Matrix Control past the expiration date. Expiration date and lot number are noted on the outside label of the box. After use, the enrichment medium and the 3M Molecular Detection Matrix Control tubes can potentially contain pathogenic materials. When testing is complete, follow current industry standards for the disposal of contaminated waste. Consult the Safety Data Sheet for additional information and local regulations for disposal.

Instructions for Use

Follow all instructions carefully. Failure to do so may lead to inaccurate results.

Periodically decontaminate laboratory benches and equipment (pipettes, cap/decap tools, etc.) with a 1-5% (v:v in water) household bleach solution or DNA removal solution.

Preparation of the 3M™ Molecular Detection Speed Loader Tray

1. Wet a cloth or disposable towel with a 1-5% (v:v in water) household bleach solution and wipe the 3M Molecular Detection Speed Loader Tray.
2. Rinse the 3M Molecular Detection Speed Loader Tray with water.
3. Use a disposable towel to wipe the 3M Molecular Detection Speed Loader Tray dry.
4. Ensure the 3M Molecular Detection Speed Loader Tray is dry before use.

Preparation of the 3M™ Molecular Detection Chill Block Insert

For detailed instructions, please refer to the Product Instructions for the specific 3M Molecular Detection Assay(s) being used.

Preparation of the 3M Molecular Detection Heat Block Insert

Place the 3M Molecular Detection Heat Block Insert in a dry double block heater unit. Turn on the dry block heater unit and set the temperature to allow the 3M Molecular Detection Heat Block Insert to reach and maintain a temperature of 100 ± 1°C.

NOTE: Depending on the heater unit, allow approximately 30 minutes for the 3M Molecular Detection Heat Block Insert to reach temperature. Using a calibrated thermometer placed in the designated location, in the upper right corner of the block, verify that the 3M Molecular Detection Heat Block Insert is at 100 ± 1°C.

Preparation of the 3M Molecular Detection Instrument

1. Launch the 3M™ Molecular Detection Software and log in. Contact your 3M Food Safety representative to ensure you have the most updated version of the software.
2. Turn on the 3M Molecular Detection Instrument.
3. Create or edit a run with data for each sample. Refer to the 3M Molecular Detection System User Manual for details.

NOTE: The 3M Molecular Detection Instrument must reach and maintain temperature of 60°C before inserting the 3M Molecular Detection Speed Loader Tray with reaction tubes. This heating step takes approximately 20 minutes and is indicated by an ORANGE light on the instrument's status bar. When the instrument is ready to start a run, the status bar will turn GREEN.

Lysis

For detailed instructions, please refer to the Product Instructions for the specific 3M Molecular Detection Assay(s) being used.

Amplification

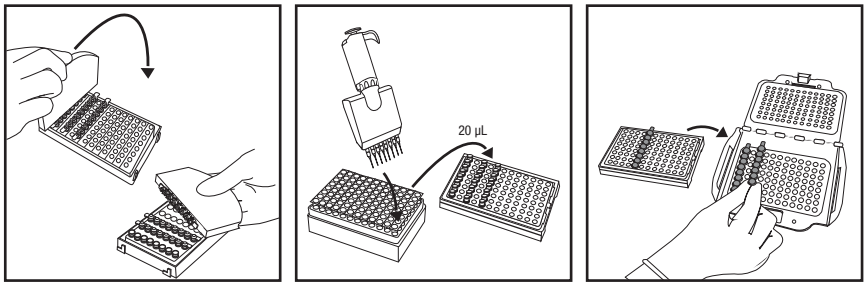
Transfer sample lysate to 3M Molecular Detection Matrix Control tubes as described below:

1. One 3M Molecular Detection Matrix Control tube is required for each matrix type.
   - 1.1 3M Molecular Detection Matrix Control tube strips can be cut to desired tube number. Select the number of individual tubes or 8-tube strips needed.
   - 1.2 Place 3M Molecular Detection Matrix Control tubes in an empty rack.
   - 1.3 Avoid disturbing the reagent pellets from the bottom of the tubes.
2. To avoid cross-contamination, decap one 3M Molecular Detection Matrix Control tube strip at a time and use a new pipette tip for each transfer step.
3. Transfer lysate to 3M Molecular Detection Matrix Control tubes as described below:
   - 3.1 Use the 3M™ Molecular Detection Cap/Decap Tool-Reagent to decap the MC tubes – one MC strip at a time. Discard cap.
   - 3.2 **Transfer 20 µL of selected Sample lysate from the upper ½ of the liquid (avoid precipitate) in the 3M Lysis Solution tube into corresponding 3M Molecular Detection Matrix Control tube.** Dispense at an angle to avoid disturbing the pellets. Mix by gently pipetting up and down 5 times to dissolve lyophilized reagent.
   - 3.3 Repeat step 3.2 until individual Sample lysate has been added to a corresponding **3M Molecular Detection** Matrix Control tube in the strip.

3.4 Cover the **3M Molecular Detection** Matrix Control tubes with the provided extra cap and use the rounded side of the 3M Molecular Detection Cap/Decap Tool-Reagent to apply pressure in a back and forth motion ensuring that the cap is tightly applied.

3.5 Repeat steps 3.1 to 3.4 as needed, for the number of selected sample matrices to be tested.

4. Load capped tubes into a clean and decontaminated 3M Molecular Detection Speed Loader Tray then close and latch the lid.



5. Review and confirm the configured run in the 3M Molecular Detection Software.
6. Click the Start button in the software and select instrument for use. The selected instrument's lid automatically opens.
7. Place the 3M Molecular Detection Speed Loader Tray into the 3M Molecular Detection Instrument and close the lid to start the assay. Results are provided within 60-75 minutes, although positives may be detected sooner.
8. After the assay is complete, remove the 3M Molecular Detection Speed Loader Tray from the 3M Molecular Detection Instrument and dispose of the tubes by soaking in a 1-5% (v:v in water) household bleach solution for 1 hour and away from the assay preparation area.

NOTICE: To minimize the risk of false-positives due to cross-contamination, never open reagent tubes containing amplified DNA. This includes Reagent Control, Reagent and 3M Molecular Detection Matrix Control tubes post amplification. Always dispose of sealed reagent tubes away from the assay preparation area.

Results and Interpretation

An algorithm interprets the light output curve resulting from the detection of the nucleic acid amplification. Results are analysed automatically by the software and are color-coded based on the result. A Valid or Inhibited result is determined by analysis of a number of unique curve parameters. Valid 3M Molecular Detection Matrix Control results indicate no inhibitory effect from the matrix sample. Valid results are reported in real-time while inhibited results will be displayed after the run is completed.

NOTE: Even an Invalid sample will not give a zero reading as the system and 3M Molecular Detection Matrix Control amplification reagents have a "background" relative light unit (RLU) reading.

3M recommends the user to repeat the assay for any inhibited samples as follows:

1. Perform a 1:2 or 1:10 dilution of the enriched sample using sterile enrichment broth. As an alternative to a 1:2 dilution, transfer 10 µL of the enrichment into the 3M Lysis Solution tubes.
2. Proceed to re-test as described in the **Lysis** and **Amplification** sections.

If you have questions about specific applications or procedures, please visit our website at www.3M.com/foodsafety or contact your local 3M representative or distributor.

References

1. ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories.
2. ISO 7218. Microbiology of food and animal feeding stuffs – General rules for microbiological examination.

Explanation of Symbols

www.3M.com/foodsafety/symbols

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