

foodproof®

StarPrep® Two

8-Strip Kit

High-Throughput

PRODUCT INSTRUCTIONS

Documentation for the high-throughput extraction of DNA
from gram-positive bacteria for direct use in PCR

Product No. KIT230186

foodproof®

StarPrep® Two 8-Strip Kit
High-Throughput

Product No. KIT230186

Kit for 480 reactions

Store kit at 15 to 25 °C

For testing of food
and environmental samples

Approval:



PRODUCT INSTRUCTIONS

Revision B, December 2024



1. OVERVIEW 4

1.1 General Information 4

1.2 Applicability..... 4

1.3 Kit Contents 5

2. INSTRUCTIONS 6

2.1 Required Material 6

2.2 Precautions and Preparations..... 8

2.3 VIAFLO 96 Program..... 9

2.4 Workflows 10

 2.4.1 Extraction Procedure A.1: STANDARD 11

 2.4.2 Extraction Procedure A.2: VIAFLO 96 14

 2.4.3 Extraction Procedure B: RAPID 17

2.5 Troubleshooting..... 20

2.6 Support..... 21

3. ADDITIONAL INFORMATION 22

3.1 General Information 22

3.2 Reference Number 23

3.3 Change Index..... 23

OVERVIEW

1. OVERVIEW

The foodproof® StarPrep® Two 8-Strip Kit is designed for the rapid preparation of DNA from gram-positive bacteria like *Listeria monocytogenes* for direct use in PCR. Up to 96 samples can be processed in parallel. The kit generates PCR template DNA from up to 800 µL of enrichment culture. The extracted DNA can be used directly in any PCR application.

The StarPrep Two Lysis Buffer eliminates the need for hazardous organic extractions or chaotropic agents. The entire DNA preparation can be performed in a single tube, minimizing handling steps and exposure to hazardous material. The reduced number of handling steps saves time and eliminating DNA-containing extract transfer steps minimizes the risk of cross-contamination.

1.1 General Information

Number of Reactions

The kit is designed for 480 reactions.

Storage Conditions

Store at 15 to 25 °C.

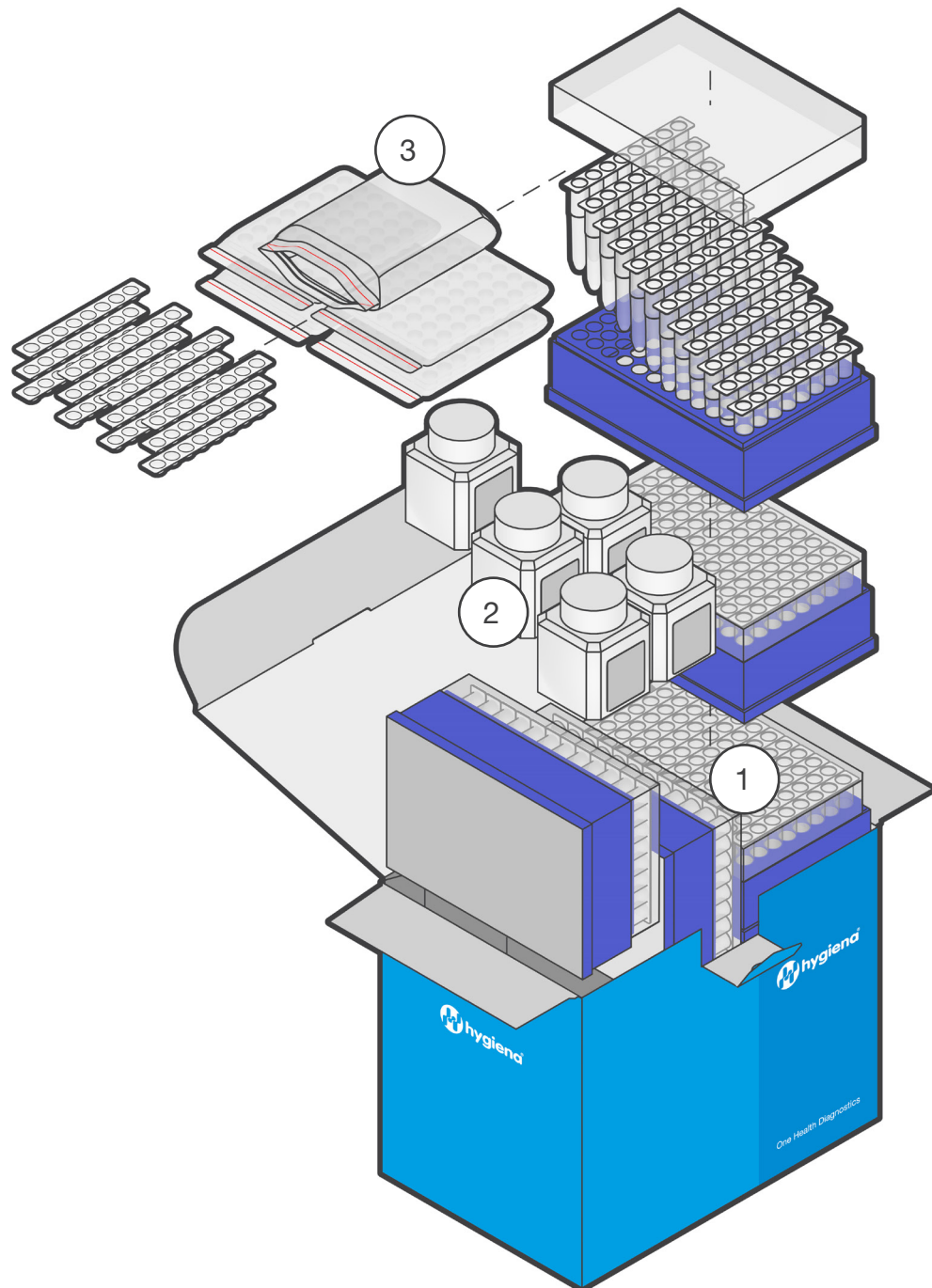
The components of the foodproof StarPrep Two 8-Strip Kit are guaranteed to be stable through the expiration date printed on the label.

1.2 Applicability

The lysis buffer can be used to prepare DNA from up to 800 µL sample. The lysis buffer is optimized for the preparation of various types of sample material. The quality of the DNA obtained with the lysis buffer is suitable for any PCR application.

OVERVIEW**1.3 Kit Contents**

A schematic representation of the foodproof StarPrep Two 8-Strip Kit with all components:

KIT230186

1. 5 x 96 micro tube rack with 8-tube strips 1.2 mL (prefilled with beads) and 8-cap strips
2. 5 bottles with 30 mL lysis buffer
3. 5 bags with 12 x 8-cap strips

2. INSTRUCTIONS

This section provides all information for a seamless DNA extraction from a variety of matrices.

2.1 Required Material

Most of the required equipment and reagents are available through Hygiena®.

Please contact us for further information.

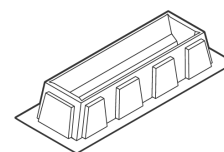


It is highly recommended to only use the materials described below to ensure the performance of the method.

Consumables

- ☐ Sterile **reservoir**, 100 mL

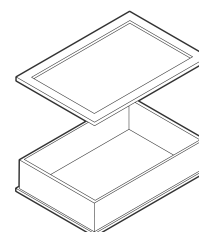
For procedures A.1: STANDARD (2.4.1) and B: RAPID (2.4.3)



- ☐ **Automation friendly reservoirs**

Sterile 150 mL, reservoir base and lid - INTEGRA Biosciences

Only for procedure A.2: VIAFLO 96 (2.4.2)*



* Use of VIAFLO 96 is not included under AOAC RI *Performance Tested Method*SM (PTM) certification.

Equipment

- ☐ **Multichannel pipette** and filter tips

e.g., 8-Channel Pipette VIAFLO - INTEGRA Biosciences);

GripTips: 50 to 1,250 µL

or EP Xplorer Plus Electronic Multichannel Pipette;

Filter Tips: 50 to 1,250 µL

For procedures A.1: STANDARD (2.4.1) and B: RAPID (2.4.3)

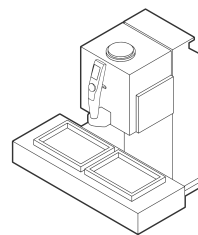


INSTRUCTIONS

☐ **Benchtop pipetting system** and deep well tips

VIAFLO 96 base unit, 96 channel pipetting head, spring-loaded plate holder A & B for 96 well plates - all INTEGRA Biosciences; GripTips in racks: 50 to 1,250 µl

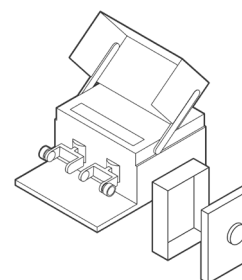
Only for procedure A.2: VIAFLO 96 (2.4.2)



☐ **Unit for mechanical cell disruption** suitable for working with 1.2 mL x 8-tube strips

MPS-1 High-Speed Multi Plate Shaker BioSan and 96 x 2 mL deepwell plate

or Mixer Mill 400 Retsch GmbH with rack adapter TissueLyser Adapter Set 2x96 Qiagen

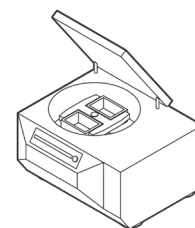


☐ **Centrifuge** with swing-out rotor for microtiter plates capable of a $> 5,400 \times g$ centrifugal force

e.g., Sigma 4-16S including rotor

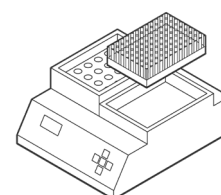
or **centrifuge** with swing-out rotor for microtiter plates capable of a $2,000 \times g$ centrifugal force

e.g., Sigma 2-7 including rotor

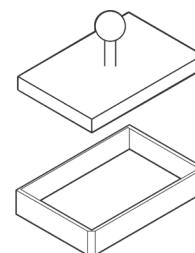


☐ **TH 21 heating block thermostat**

☐ **Exchange block** for deepwell plates for TH 21

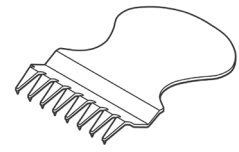


☐ **Lid weight** with **incubation frame** for TH 21 heating block thermostat



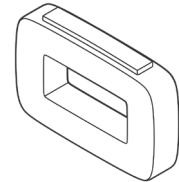
INSTRUCTIONS

☐ Decapper 8-strip



Recommended:

☐ Cap installing tool



2.2 Precautions and Preparations

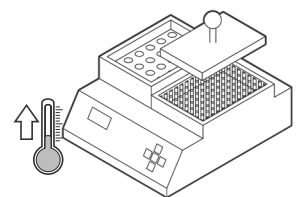
Follow all universal safety precautions governing work with biohazardous materials, e.g., wear lab coats and gloves at all times. Properly dispose of all contaminated materials, decontaminate work surfaces and use a biosafety cabinet whenever aerosols might be generated.

For more information, please refer to the appropriate material safety data sheet (SDS). The SDS is available online at www.hygiena.com/sds.

☐ Always use filter tips in order to avoid cross-contamination.



☐ To reach the required temperature of 95 - 100 °C in the tubes for the lysis step of the bacteria, the temperature of the corresponding **heating unit TH 21** has to be set to **100 °C**.



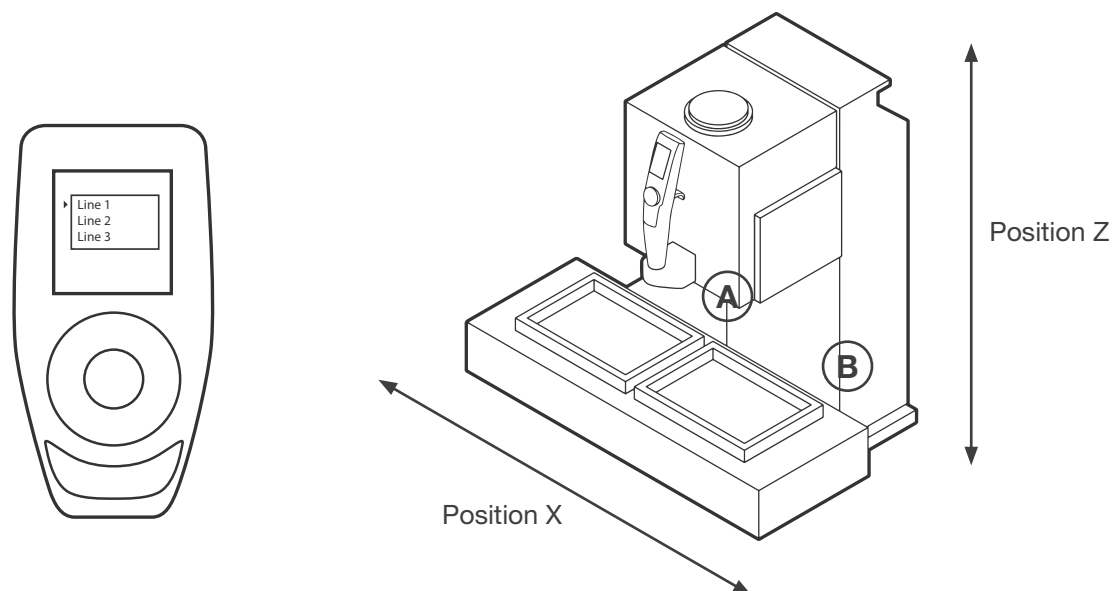
INSTRUCTIONS

2.3 VIAFLO 96 Program

Note: Use of the VIAFLO 96 is not included under AOAC RI PTM certification.

The VIAFLO 96 is a pipetting system, which enables the transfer of 96 samples in a single step. The following table shows how to program the instrument for the extraction procedure

A.2: VIAFLO 96 (2.4.2)



Step	Action	PositionX	PositionZ	Line1	Line2	Line3	Volume	Speed	Cycles
1	Move (X,Z)	79.5	192.5						
2	Prompt			POSITION	A RACK	B TIP BOX			
3	Tip Change								
4	Move (X,Z)	-80	192.5						
5	Prompt			POSITION B	EMPTY	WASTE BOX			
6	Move (X,Z)	-80	90						
7	Aspirate						300	1	
8	Move (X,Z)	-80	80						
9	Aspirate						350	1	
10	Move (X,Z)	79.5	192.5						
11	Move (X,Z)	79.5	90						
12	Purge							5	
13	Prompt			POSITION A	REMOVE	RACK			
14	Prompt			NEXT	EXTERNAL	STEP 8*			

Note: *Continue with step 8 of the extraction procedure A.2: VIAFLO 96

INSTRUCTIONS

Step	Action	PositionX	PositionZ	Line1	Line2	Line3	Volume	Speed	Cycles
15	TipChange								
16	Move (X,Z)	-80	192.5						
17	Prompt			POSITION B	EMPTY	WASTE BOX			
18	Move (X,Z)	79.5	192.5						
19	Prompt			POSITION A	RESERVOIR	LYSIS BUF			
20	Move (X,Z)	-80	72.5						
21	Mix						250	5	10
22	Aspirate						300	1	
23	Move (X,Z)	79.5	192.5						
24	Prompt			POSITION A	REMOVE	RESERVOIR			
25	Prompt			POSITION A	ADD	RACK			
26	Move (X,Z)	-80	90						
27	Dispense						300	10	
28	Move (X,Z)	-80	80						
29	Mix						300	10	10
30	Move (X,Z)	79.5	192.5						
31	Move (X,Z)	79.5	90						
32	Prompt			NEXT	EXTERNAL	STEP 10			
33	Prompt			QUIT AND REMOVE TIPS					

Note: RACK = tube rack

2.4 Workflows

Procedure A.1: STANDARD describes the DNA extraction from up to 800 µL enrichment culture using 8-strip tubes and multichannel pipettes. This procedure is a more sensitive protocol.

The A.2: VIAFLO 96 protocol includes the VIAFLO 96 as a pipetting device, which enables the transfer of 96 samples in a single step.

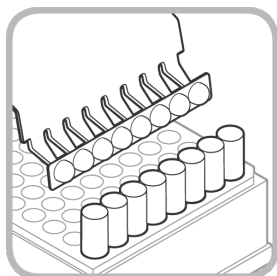
In the B: RAPID protocol, 100 µL sample is added directly to the pre-aliquoted lysis buffer, without an initial centrifugation step, saving time and effort.

EXTRACTION PROCEDURE A.1: STANDARD**2.4.1 EXTRACTION PROCEDURE A.1: STANDARD**

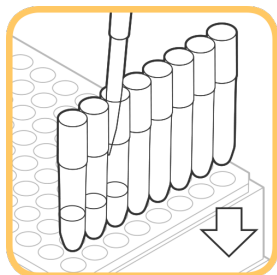
This protocol is intended for extracts that will be used in combination with foodproof kits.

**1. SHAKE SAMPLE**

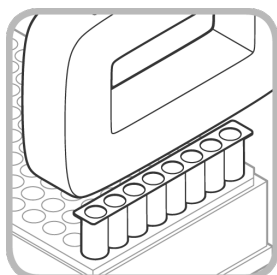
Shake enrichment culture gently and let suspension settle for 5 to 10 min.

**2. REMOVE CAPS**

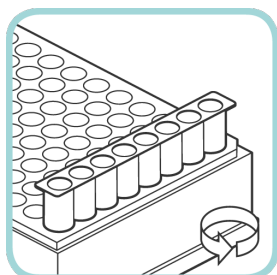
Remove and discard the 8-cap strips from the 8-tube strips.
To minimize the contamination risk, use the decapper 8-strip tool.

**3. ADD SAMPLE**

Transfer **up to 800 µL** sample (enrichment culture supernatant) to the 8-tube strips.

**4. SEAL TUBES**

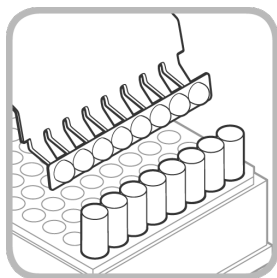
Seal the tubes with sterile cap strips.

**5. CENTRIFUGE RACK**

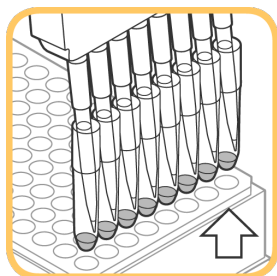
10 min at 5,400 x g (or 25 min at 2,000 x g).

Make sure the rack is not sealed with rack lid during centrifugation.

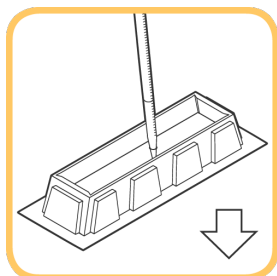
Note: Time and g-force depend on the centrifuge (please see 2.1. Required Material for more information). Set the centrifuge acceleration to maximum speed and the brake to medium. If necessary, centrifugation forces should be calculated according to the centrifuge manual used.

EXTRACTION PROCEDURE A.1: STANDARD**6. REMOVE CAPS**

Remove and discard the 8-cap strips from the 8-tube strips.
To minimize the contamination risk, use the decapper 8-strip tool.

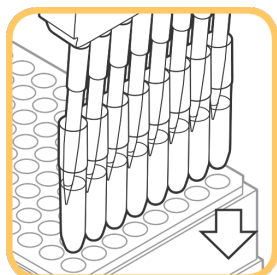
**7. REMOVE SUPERNATANT**

Remove **up to 650 µL** supernatant carefully with a multichannel pipette immediately after centrifugation, discard and inactivate appropriately.
150 µL has to remain in the tube.
Take care that the tips of the pipette in the reaction tubes are not touching the pellets.

**8. PREPARE LYSIS BUFFER**

Transfer required lysis buffer to a sterile reservoir.
Prepare **300 µL** lysis buffer per sample plus **1 mL** lysis buffer as dead volume.

Note: Shake the bottle with lysis buffer gently in a short time interval to avoid sedimentation of ingredients.

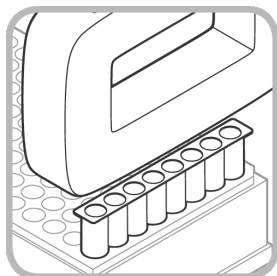
**9. ADD LYSIS BUFFER AND MIX**

Pipette lysis buffer up and down 5 to 10 times in reservoir before using it to avoid sedimentation of ingredients.

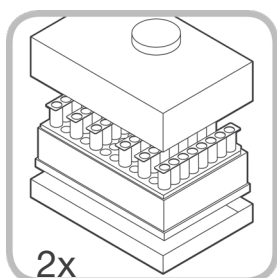
Transfer **300 µL** lysis buffer with a multichannel pipette to each tube.

Resuspend pellets by pipetting up and down 5 to 10 times.

Note: For optimal DNA isolation efficiency, pellet has to be completely resuspended.

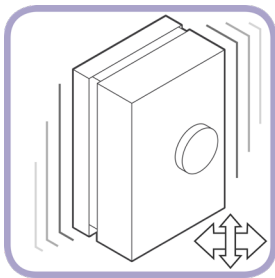
**10. SEAL TUBES**

Seal the tubes **tightly** with **new** sterile cap strips.

**11. INSTALL ADAPTER SET**

Place the rack **without rack lid** in the TissueLyser Adapter Set.

Note: Split the tube strips into 2 groups and place them into two tube racks to prepare appropriate counterweights for disruption. Place the tube strips into the racks in an even and balanced manner. Make sure each rack contains at least two strips placed in the outermost positions (row 1 and 12 of the rack). If you prepare only a few samples (less than 4 strips), it is necessary to use additional tube strips prefilled with 450 µL water to balance it out.



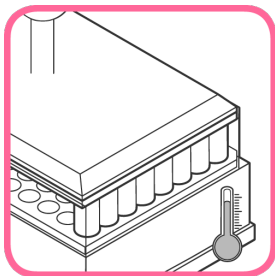
12. MECHANICAL DISRUPTION

Place the 2 adapters in the cell disruption unit and run mechanical disruption.

MPS-1: 8 min at 2,100 rpm.

Mixer Mill 400: 8 min at 30 Hz.

The efficiency of disruption depends on the mechanical cell disruption unit.



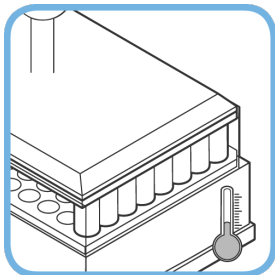
13. INCUBATE

Remove tube rack bottom and install incubation frame.

Incubate rack with tube strips **5 min at 100 °C** in the TH 21 Heating Block for 8-tube strips.

Weigh caps down with the lid weight.

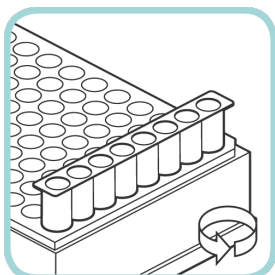
Note: To avoid removing and reinstalling the bottom, it is possible to place tube strips in an empty micro tube rack (with rack bottom removed).



14. CHILL

Carefully **remove** the rack with the **tube strips together with the lid weight** from the heating unit and let it **cool 3 - 5 min at room temperature**.

To avoid opening of caps, do not remove the lid weight until the strips have cooled down.



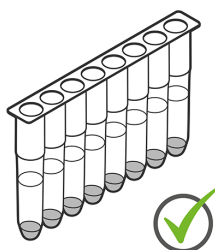
15. CENTRIFUGE RACK

Reinstall tube rack bottom.

Centrifuge **5 min at 5,400 x g** (or 10 min at 2,000 x g).

Make sure the rack is not sealed with rack lid during centrifugation.

Note: Time and g-force depend on the centrifuge (please see 2.1 Required Material for more information). Set the centrifuge acceleration to maximum speed and the brake to medium. If necessary, centrifugation forces should be calculated according to the centrifuge manual used.



SUPERNATANT FOR DETECTION

Use 5 µL supernatant in combination with foodproof PCR Kits.

Note: Strictly avoid transferring fractions of the sediment to the PCR reaction because this might cause PCR inhibition.

For later analysis, store DNA at -15 to -25 °C.

After thawing, mix briefly by vortexing and centrifuge at 2,000 x g for 10 min.

Note: The sample is not purified. Proteins, RNA and other materials remain in the sample. Long-term storage or archival of prepared DNA samples is not recommended.

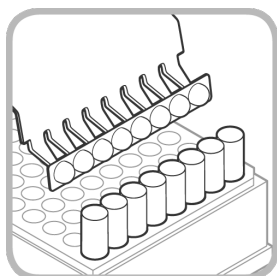
EXTRACTION PROCEDURE A.2: VIAFLO 96**2.4.2 EXTRACTION PROCEDURE A.2: VIAFLO 96**

Note: Use of the VIAFLO 96 is not included under AOAC RI PTM certification.

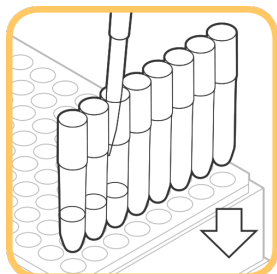
The following protocol describes the DNA extraction from 800 µL enrichment culture using the VIAFLO 96 instrument. This procedure is equivalent to STANDARD (2.4.1.).

**1. SHAKE SAMPLE**

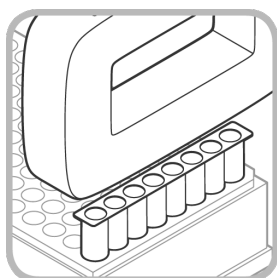
Shake enrichment culture gently and let suspension settle for 5 to 10 min.

**2. REMOVE CAPS**

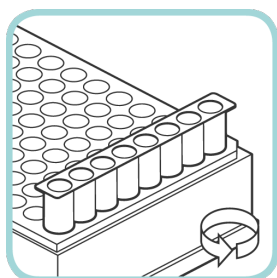
Remove and discard the 8-cap strips from the 8-tube strips.
To minimize the contamination risk, use the decapper 8-strip tool.

**3. ADD SAMPLE**

Transfer **up to 800 µL** sample (enrichment culture supernatant) to the 8-tube strips.

**4. SEAL TUBES**

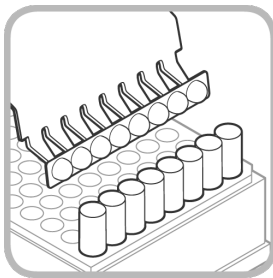
Seal the tubes with sterile cap strips.

**5. CENTRIFUGE RACK**

10 min at 5,400 x g (or 25 min at 2,000 x g).

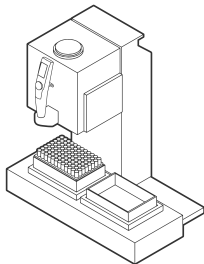
Make sure the rack is not sealed with rack lid during centrifugation.

Note: Time and g-force depend on the centrifuge (please see 2.1 Required Material for more information). Set the centrifuge acceleration to maximum speed and the brake to medium. If necessary, centrifugation forces should be calculated according to the centrifuge manual used.



6. REMOVE CAPS

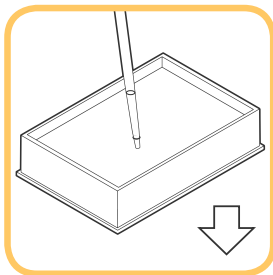
Remove and discard the 8-cap strips from the 8-tube strips.
To minimize the contamination risk, use the decapper 8-strip tool.



7. START VIAFLO 96 PROGRAM

Switch on the VIAFLO 96 instrument. Start program “custom/SPTWO8_A2” and follow the instructions. Run protocol step 1 to step 14.

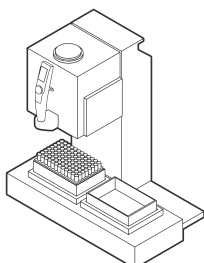
Note: Step “Tip Change” means to discard any used tips, to remove the waste box from position B and to add a tip box at position B.



8. PREPARE LYSIS BUFFER

Transfer required lysis buffer to a sterile VIAFLO 96 reservoir.
Prepare **300 µL** lysis buffer per sample plus **5 mL** lysis buffer as dead volume.

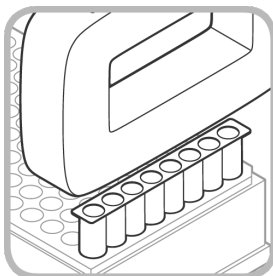
Note: Shake the bottle with lysis buffer gently during use to avoid sedimentation of ingredients.



9. CONTINUE VIAFLO 96 PROGRAM

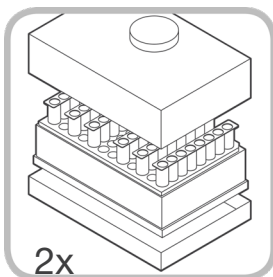
Run protocol step 15 to step 33.

Note: Step “Tip Change” means to discard any used tips, to remove the waste box from position B and to add a tip box at position B.



10. SEAL TUBES

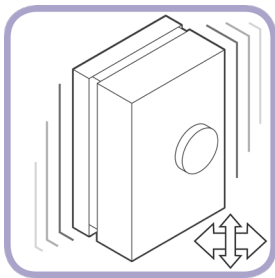
Seal the tubes **tightly** with new sterile cap strips.



11. INSTALL ADAPTER SET

Place the rack **without rack lid** in the TissueLyser Adapter Set.

Note: Split the tube strips into 2 groups and place them into two tube racks to prepare appropriate counterweights for disruption. Place the tube strips into the racks in an even and balanced manner. Make sure each rack contains at least two strips placed in the outermost positions (row 1 and 12 of the rack). If you prepare only a few samples (less than 4 strips), it is necessary to use additional tube strips prefilled with 450 µL water to balance the weight.



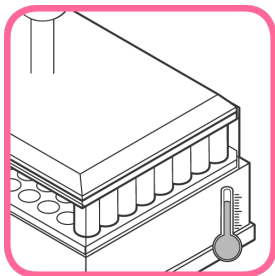
12. MECHANICAL DISRUPTION

Place the 2 adapters in the cell disruption unit and run mechanical disruption.

MPS-1: 8 min at 2,100 rpm.

Mixer Mill 400: 8 min at 30 Hz.

The efficiency of disruption depends on the mechanical cell disruption unit.



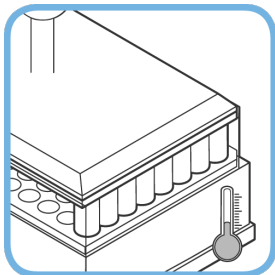
13. INCUBATE

Remove tube rack bottom and install incubation frame.

Incubate rack with tube strips **5 min at 100 °C** in the TH 21 Heating Block for 8-tube strips.

Weigh caps down with the lid weight.

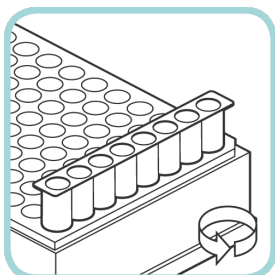
Note: To avoid removing and reinstalling the bottom, it is possible to place tube strips in an empty micro tube rack (with rack bottom removed).



14. CHILL

Carefully **remove** the rack with both the **tube strips and the lid weight** from the heating unit and let it **cool 3 - 5 min at room temperature**.

To avoid opening of caps, do not remove the lid weight until the strips have cooled down.



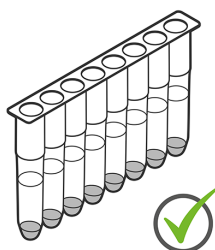
15. CENTRIFUGE RACK

Reinstall tube rack bottom.

Centrifuge **5 min at 5,400 x g** (or 10 min at 2,000 x g).

Make sure the rack is not sealed with the rack lid during centrifugation.

Note: Time and g-force depend on the centrifuge (please see 2.1. Required Material for more information). Set the centrifuge acceleration to maximum speed and the brake to medium. If necessary, centrifugation forces should be calculated according to the centrifuge manual used.



SUPERNATANT FOR DETECTION

Use only 5 µL supernatant in combination with foodproof PCR Kits.

Note: Strictly avoid transferring fractions of the sediment to the PCR reaction because this might cause PCR inhibition.

For later analysis, store DNA at -15 to -25 °C.

After thawing, mix briefly by vortexing and centrifuge at 2,000 x g for 10 min.

Note: The sample is not purified. Proteins, RNA and other materials remain in the sample. Long-term storage or archival of prepared DNA samples is not recommended.

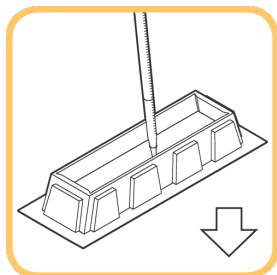
2.4.3 EXTRACTION PROCEDURE B: RAPID

This protocol is intended for rapid high-throughput extraction in combination with foodproof kits.



1. SHAKE SAMPLE

Shake enrichment culture gently and let suspension settle for 5 to 10 min.

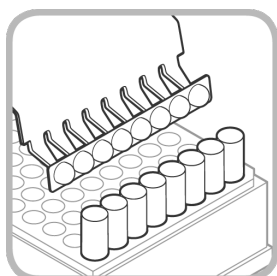


2. PREPARE LYSIS BUFFER

Transfer required lysis buffer to a sterile reservoir.

Prepare **300 µL** lysis buffer per sample plus **1 mL** lysis buffer as dead volume.

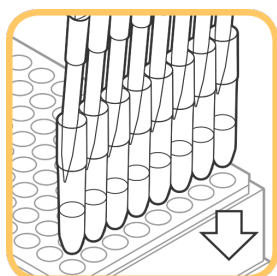
Note: Shake the bottle with lysis buffer gently in a short time interval to avoid sedimentation of ingredients.



3. REMOVE CAPS

Remove and discard the 8-cap strips from the 8-tube strips.

To minimize the contamination risk, use the decapper 8-strip tool.

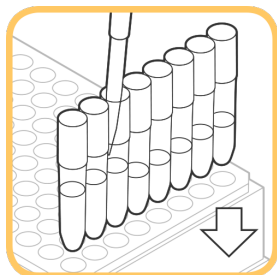


4. ADD LYSIS BUFFER

Transfer **300 µL** lysis buffer with a multichannel pipette to each tube.

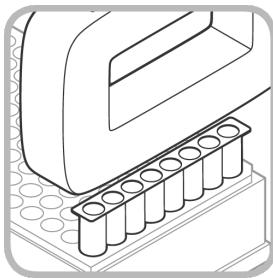
Pipette lysis buffer up and down in reservoir before using to avoid sedimentation of ingredients.

For this protocol, it is possible to pre-fill up to 12 strips (96 reactions) at once, store at room temperature and use until the end of the shelf life. Close the filled tubes thoroughly with the cap strips from step 3 to avoid evaporation of lysis buffer.



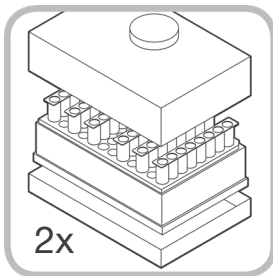
5. ADD SAMPLE

Transfer **100 µL** sample (enrichment culture supernatant) to the 8-tube strips.



6. SEAL TUBES

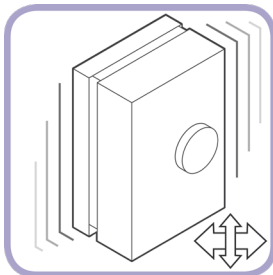
Seal the tubes **tightly** with sterile cap strips.



7. INSTALL ADAPTER SET

Place the rack **without rack lid** in the TissueLyser Adapter Set.

Note: Split the tube strips into 2 groups and place them into two tube racks to prepare appropriate counterweights for disruption. Place the tube strips into the racks in an even and balanced manner. Make sure each rack contains at least two strips placed in the outermost positions (row 1 and 12 of the rack). If you prepare only a few samples (less than 4 strips), it is necessary to use additional tube strips prefilled with 450 µL water to balance the weight.



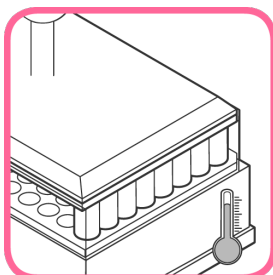
8. MECHANICAL DISRUPTION

Place the 2 adapters in the cell disruption unit and run mechanical disruption.

MPS-1: 8 min at 2,100 rpm.

Mixer Mill 400: 8 min at 30 Hz.

The efficiency of disruption depends on the mechanical cell disruption unit.



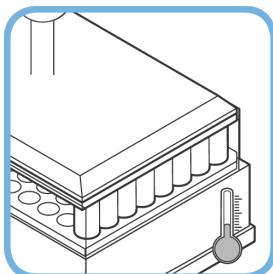
9. INCUBATE

Remove tube rack bottom and install incubation frame.

Incubate rack with tube strips **5 min at 100 °C** in the TH 21 Heating Block for 8-tube strips.

Weigh caps down with the lid weight.

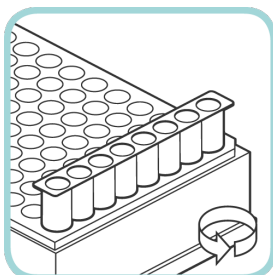
Note: To avoid removing and reinstalling the bottom piece, it is possible to place tube strips in an empty micro tube rack (with rack bottom removed).



10. CHILL

Carefully **remove** the rack with both the **tube strips together and the lid weight** from the heating unit and let it **cool 3 - 5 min at room temperature**.

To avoid opening of caps, do not remove the lid weight until the strips have cooled down.



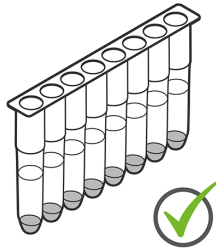
11. CENTRIFUGE RACK

Reinstall tube rack bottom.

Centrifuge **5 min at 2,000 x g**.

Make sure the rack is not sealed with rack lid during centrifugation.

Note: Time and g-force depend on the centrifuge (please see 2.1. Required Material for more information). Set the centrifuge acceleration to maximum speed and the brake to medium. If necessary, centrifugation forces should be calculated according to the centrifuge manual used.



SUPERNATANT FOR DETECTION

Use 5 µL extract for the respective foodproof PCR Kit/LyoKit.

Note: Strictly avoid transferring fractions of the sediment to the PCR reaction because this might cause PCR inhibition.

For later analysis, store DNA at -15 to -25 °C.

After thawing, mix briefly by vortexing and centrifuge at 2,000 × g for 5 min.

Note: The sample is not purified. Proteins, RNA and other materials remain in the sample. Long-term storage or archiving of prepared DNA samples is not recommended.

2.5 Troubleshooting

Problem	Possible Cause	Recommendation
Extract inhibits PCR.	Enrichment culture or sample contains too many PCR inhibitors.	Perform a subcultivation, e.g., 1:10 dilution in fresh enrichment broth. Repeat DNA extraction with a reduced sample volume.
	DNA extract contains too many PCR inhibitors.	Dilute DNA extract, e.g., 1:10, or reduce the amount of extracted DNA.
	Some of the centrifugation pellet transferred over to the PCR.	Always centrifuge the DNA sample before performing PCR. Do not allow the filter tip to contact the pellet.
	Supernatants are not completely removed.	Remove supernatants completely (e.g., after Reagent D treatment).
Low DNA yield.	Improper storage of kit components.	Store kit reagents at 15 to 25 °C.
	Enrichment culture contains substances that reduce the DNA extraction efficiency.	Perform a subcultivation or dilution, e.g., 1:10 in fresh enrichment broth.
	Sample contains substances that reduce the DNA extraction efficiency.	Reduce the sample volume.
	Not enough target organisms in enrichment culture.	Prolong the incubation period.
	Pellet resuspension incomplete.	Improve resuspension by prolonged pipetting or vortexing.
	Suboptimal reaction conditions.	Ensure proper heating conditions. Verify correct temperature of the heating block with a thermometer.
Lid of the reaction tube opens during or after heating.	Reaction tube not firmly closed or not enough weight exerted on the caps of the tube strips.	Ensure that all reaction tubes are firmly closed before heating. Weigh the caps down during heating and do not remove the weight until the tubes have cooled down.

2.6 Support

If you have questions or experience any problems with our products, please contact us:



www.hygiena.com/support

Our aim is to provide you with a solution as quickly and effectively as possible. We would also like you to contact us if you have any suggestions for improving the product or in case you would like to use our product for a different application. We highly value your feedback.

ADDITIONAL INFORMATION

3. ADDITIONAL INFORMATION

3.1 General Information

Quality Control

All products are regularly monitored by our quality control. You can find the certificate of analysis (COA) on our website. If you would like to carry out your own quality control, you will find the analysis method described in the certificate.

Waste Disposal

All contaminated and potentially infectious material, like enrichment cultures or food samples, should be autoclaved before disposal and eliminated according to local rules and regulations. For proper disposal of unused chemicals, please refer to the SDS.

Warranty and Disclaimer of Liability

“Limited Warranty” and “Disclaimer of Liability”: Hygiena Diagnostics GmbH warrants that this product is free from defects in materials and workmanship through the expiration date printed on the label and only if the following are complied with:

- (1) The product is used according to the guidelines and instructions set forth in the product literature;
- (2) Hygiena Diagnostics GmbH does not warrant its product against any and all defects when: the defect is as a result of material or workmanship not provided by Hygiena Diagnostics GmbH; defects caused by misuse or use contrary to the instructions supplied, or improper storage or handling of the product;
- (3) All warranties of merchantability and fitness for a particular purpose, written, oral, expressed or implied, shall extend only for a period of one year from the date of manufacture. There are no other warranties that extend beyond those described on the face of this warranty;
- (4) Hygiena Diagnostics GmbH does not undertake responsibility to any purchaser of its product for any undertaking, representation or warranty made by any dealers or distributors selling its products beyond those herein expressly expressed unless expressed in writing by an officer of Hygiena Diagnostics GmbH;
- (5) Hygiena Diagnostics GmbH does not assume responsibility for incidental or consequential damages, including, but not limited to responsibility for loss of use of this product, removal or replacement labor, loss of time, inconvenience, expense for telephone calls, shipping expenses, loss or damage to property or loss of revenue, personal injuries or wrongful death;
- (6) Hygiena Diagnostics GmbH reserves the right to replace or allow credit for any modules returned under this warranty.

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3.2 Reference Number

The reference number and original Hygiena Diagnostics GmbH article number: S 400 17 L.

3.3 Change Index

Version 1, February 2016:

New document.

Version 2, January 2019:

Protocol and information about additional equipment added.

Version 3, November 2019:

New document layout and content.

Version 4, February 2022:

Rebranding.

Revision A, September 2023:

Additional formatting, minor content and product number update.

S 400 17 L 20 -> INS-KIT230186-REVA

Revision B, December 2024:

Clarification of AOAC RI PTM certification.

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