

# Bovine Spongiform Encephalopathy (BSE) Antigen Test Kit, Immuno-chromatographic Assay Prionics®-Check PrioSTRIP

Test for *in vitro* detection of TSE-related PrP<sup>Sc</sup>

Within the European Union, this test is approved as rapid test for the BSE testing program on cattle which is set up in accordance with Regulation (EC) No 999/2001

Kit for 470 samples  
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Version 4.0\_e\_cfia

## Package Insert

For *in-vitro* veterinary diagnostic use only

Store at 5±3°C

Product No.: 30000

The producer of the rapid tests must have a quality assurance system in place agreed by the Community Reference Laboratory (CRL), which ensures that the test performance does not change. The producer must provide the test protocol to the CRL. Sampling tools and modifications to the rapid test or to the test protocol (including sampling) may only be made following advance notification to the CRL and provided that the CRL finds that the modification does not reduce the sensitivity, specificity or reliability of the rapid test. That finding shall be communicated to the Commission and to the national reference laboratories.

## Introduction

Various tissues of prion-infected animals contain a pathologically altered, disease-specific form of the normal prion protein (PrP). The altered prion protein is called PrP<sup>Sc</sup>. The normal isoform of PrP is termed PrP<sup>C</sup> (the cellular form of PrP).

PrP<sup>Sc</sup> differs from PrP<sup>C</sup> in its protease resistance. Upon treatment with protease, PrP<sup>C</sup> is degraded, while PrP<sup>Sc</sup> is reduced from its original size of 32 – 35 kD to a smaller size of 27 – 30 kD. The remaining protease-resistant PrP<sup>Sc</sup> fragment is referred to as PrP 27 – 30.

The Prionics®-Check PrioSTRIP is an immuno-chromatographic assay which detects PrP<sup>Sc</sup> in brain tissue homogenates. Prionics®-Check PrioSTRIP achieves its high precision and reliability through the unique properties of the buffer solutions and the high affinities of the two monoclonal antibodies directed against the prion protein.

After sample collection and registration, samples are analyzed with the Prionics®-Check PrioSTRIP immuno-chromatographic assay. The Prionics®-Check PrioSTRIP follows a four step protocol, consisting of homogenization, protease digestion, preincubation and detection. 470 homogenized samples can be analyzed in less than 2½ hours.

Samples are collected, registered, and a homogenate is prepared from a defined piece of tissue (medulla oblongata) of the obex region in the brain stem. Treatment with proteinase K degrades PrP<sup>C</sup> completely while PrP<sup>Sc</sup> is reduced to the 27 – 30 kD fragment. The proteolytic reaction is stopped, and PrP<sup>Sc</sup> is detected in the Prionics®-Check PrioSTRIP assay.

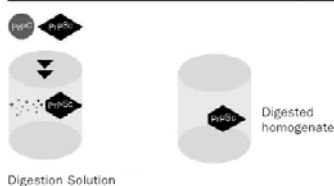
Digested homogenates are incubated with the antibody conjugate. PrP<sup>Sc</sup> present in the homogenates binds to the conjugate, which is a latex bead-labeled monoclonal antibody. By dipping the PrioSTRIP into the sample-conjugate-mixture, the flow through the membrane is started. PrP-conjugate complexes are retained at the test line by the second (capture) antibody. Uncomplexed conjugate is bound at the control line serving as a control for the proper performance of the immuno-chromatographic assay.

## Test Principle

### 1. SAMPLING + HOMOGENIZATION 45 sec



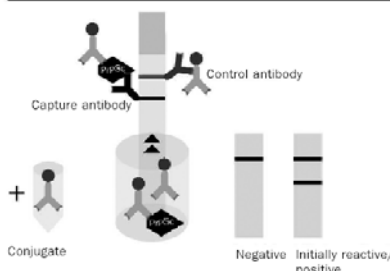
### 2. DIGESTION 60 min



### 3. PREINCUBATION 15 min



### 4. DETECTION 20 min



## Kit Components

Store kit at 5±3°C until expiry date. See kit label for actual expiry date. The shelf life of diluted, opened or reconstituted components is noted below, when appropriate. Chemical hazard data are available in section "Safety Regulations and R&S Statements" (Appendix IV).

### Component 1 Homogenization Buffer (5x)

(5x concentrated, dilute before use) Three bottles containing 220 ml of 5x concentrated Homogenization Buffer each. Prepare 1x homogenization working solution by mixing 1 part Homogenization Buffer (5x) with 4 parts purified water.

Shelf life of the 1x homogenization working solution:

1 week at 5±3°C.

Cap color code: purple

### Component 2 Digestion Buffer (Ready-to-use)

One vial containing 7.5 ml of Digestion Buffer.

Cap color code: white

### Component 3 Digestion Plates (Colorless Plates)

Five Colorless Plates in which the protease digestion is performed.

### Component 4 Sealing Film

10 pieces of Sealing Film to cover the Digestion Plates during incubations.

### Component 5 Proteinase K (Ready-to-use)

One vial containing 7.5 ml of Proteinase K for the digestion of normal PrP<sup>C</sup> during protease digestion.

Cap color code: yellow

### Component 6

#### Digestion Stop (Ready-to-use)

One vial containing 7.5 ml of Proteinase K blocker to stop the proteolytic activity of the Proteinase K.

Cap color code: red

### Component 7

#### Assay Buffer (Ready-to-use)

One bottle containing 80 ml Assay Buffer

Color of solution: green

**Place at 22±3°C at least 2 h prior to use.**

Visually check for precipitates before use.

### Component 8

#### Test Plates (White Plates)

Five white flat-bottom microplates in which PrioSTRIP® detection is performed.

### Component 9

#### Conjugate Buffer (Ready-to-use)

One bottle containing 50 ml of Conjugate Buffer.

Cap color code: blue

### Component 10

#### Conjugate (Lyophilized)

Five vials containing the lyophilized blue Conjugate. The Conjugate is reconstituted by adding 9 ml Conjugate Buffer (Component 9). Mix immediately by vortexing vigorously for at least 15 sec upon addition of conjugate buffer and just prior to each use.

Shelf life of the reconstituted Conjugate: 1 week at 5±3°C.

### Component 11

#### PrioSTRIP® Combs

Ten pouches containing six combs each. With each PrioSTRIP® comb 8 samples can be analyzed.

Return unused PrioSTRIP® combs to their pouch, close pouch and store at 5±3°C.

**Adjust to 22± 3°C for at least 30 min prior to opening the pouch.**

Shelf life in opened pouches: 2 weeks at 5±3°C.

### Component 12

#### Positive Control (Lyophilized)

Five vials containing the lyophilized functional Positive Control. One vial of functional Positive Control is reconstituted by adding first 200 µl purified water and then 200 µl Assay Buffer (Component 7). Mix by vortexing thoroughly and inverting the tube several times.

Shelf life of the reconstituted Control: 12 hours at 22±3°C.

Cap color code: red

### Component 13

#### Negative Control (Lyophilized)

Five vials containing the lyophilized Negative Control. One vial of Negative Control is reconstituted by adding first 200 µl purified water and then 200 µl Assay Buffer (Component 7). Mix by vortexing thoroughly and inverting the tube several times.

Shelf life of the reconstituted Control: 12 hours at 22±3°C.

Cap color code: white

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## Additional Kit Contents:

- Five PrioSTRIP® Visual Interpretation Sheets. Make photocopies if necessary.
- Package Insert
- PrioSTRIP® lot calibration sheet

## Additional Material Required

The **highlighted** items have been validated for the use with the PrioSTRIP®. The use of different devices is in the responsibility of the user.

### General:

Laboratory equipment according to national safety regulations.

- Purified water: at least equivalent to Grade 3 water as defined by ISO 3696:1987 (E)
- Single channel pipette (10 – 100 µl)
- Single channel pipette (100 – 1000 µl)
- Single channel pipette (1 – 5 ml)
- Multichannel pipette (5 – 50 µl)
- Multichannel pipette (50 – 300 µl)
- Pipette tips (as recommended by pipette manufacturer)
- Solution reservoirs
- 15 ml conical tubes
- Vortex

### Homogenization:

- Cutting tool and forceps
- Balance
- Dispenser for homogenization working solution
- 1.2 ml 96-deep well plate (used as sample Master Plate)
- **PrioGENIZER™** (homogenization device with six racks and one tray; Prionics AG, Product No.: 10000) and **PrioCLIP™** homogenization containers (Prionics AG, Product No.: 10010).

Or

**FASTH/ FASTH 2/MediFASTH** homogenization device (Consul, Product No.: 80040, 82040, 80020) and **Prypcon** homogenization container (Consul, Product No.: 80300)

### Digestion:

- Microplate incubator (reaching at least 50°C)

### Preincubation:

- If required, the functional Positive Control (Prionics AG, Product No.: 30000-12) and Negative Control (Prionics AG, Product No.: 30000-13) can be ordered separately with indication of kit lot number. Please note that only Controls with the same lot number as the Controls in the kit can be used.

### Analysis of Results:

**PrioSCAN® device and software** (Prionics AG, Product No.: 30900)

## Test Procedure

### Precautions

National guidelines for working with prions must be strictly followed (see also section "Safety Regulations and R&S Statements" Appendix IV). The Prionics®-Check PrioSTRIP must be performed in laboratories suited for this purpose.

Persons performing the test have to be trained generally in working with prions and specifically in performing the Prionics®-Check PrioSTRIP.

Samples should be considered as potentially infectious and all items which contact the samples as potentially contaminated.

Chemical hazard data are available in section "Safety Regulations and R&S Statements" (Appendix IV).

### Notes

To achieve optimal results with the Prionics®-Check PrioSTRIP, the following aspects must be considered:

- **The Test Procedure protocol must be strictly followed.**
- Pipette tips have to be changed for every pipetting step.
- The use of either pipette filter tips or separate pipettes for the different pipetting steps is strongly recommended. In addition, the accuracy of pipettes should be calibrated regularly.
- Separate solution reservoirs must be used for each reagent.
- All solutions, except those for preparation of digestion solution, homogenates from the homogenization containers and control samples, can be pipetted with multichannel pipettes.
- Kit components must not be used after their expiry date or if changes in their appearance are observed.
- Kit components of different kit lot numbers must not be used together.
- Purified water must be used for the test
- Non-disposable cutting tools and forceps must be decontaminated according to guidelines enforced by national authorities.

## SAMPLING AND HOMOGENIZATION

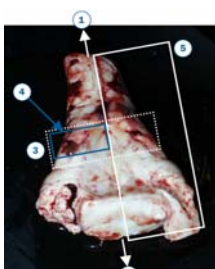
- Take 0.45-0.70 g nervous tissue from the preferred area of the left **or** the right side of the brainstem with e.g. a scalpel and weigh the sample to ensure the correct amount.

Sampling and laboratory testing must follow the Regulation (EC) No. 999/2001 Chapter C which refers in terms of collection of samples to the latest edition of the "Manual Standards for Diagnostic Test and Vaccines of the International Office of Epizootic Diseases (OIE)" stating: "The preferred sample for immunoassay should be at, or as close to the obex as possible, but no further than 1.5 cm anterior to the obex" The picture below shows the sampling area within box 4.

### Medulla oblongata (obex region)

The tissue sample is an approx. 8 cm long piece of brain stem / cervical spinal cord.

Note: after sample collection, a complete hemi-section of the brain stem with an intact obex region must remain available for confirmatory testing



- 1) spinal cord
- 2) brain
- 3) obex region
- 4) area to be used for PrioSTRIP® testing
- 5) area to be used by the BSE Reference Center

### HOMOGENIZATION:

#### Preparatory Steps

- Dilute 5x Homogenization Buffer (Component 1) with ultrapure water to prepare homogenization working solution (Appendix I).

#### Homogenization

- Transfer sample to homogenization container and determine weight on balance (0.45 - 0.70 g).
- Add ten volumes of homogenization working solution (w/v; e.g. 5 ml to 0.50 g brain tissue from the obex region) and homogenize sample using the PrioGENIZER™ or FASTH/FASTH2/MediFASTH homogenization device (45±5 sec, 20'000 ± 1'000 rpm).
- Store a 1 ml sample per homogenate in a 96-well sample Master Plate (omit wells A1 and B1, Appendix II).
- PrioCLIP™ and Prypcon homogenization containers of samples tested "TSE negative" may be

washed for reuse (see PrioCLIP™/Prypcon Wash Protocol, Appendix III).

## PROTEASE DIGESTION

### Preparatory Steps

- Set the temperature of the microplate incubator to 47±1°C approx. 1 hour prior to use.
- Prepare digestion solution (See Appendix I). Shelf life: 15 min at 22±3°C.
- Add 50 µl of digestion solution to each well of the Digestion Plate (Component 3, Colorless Plate). Omit wells A1 and B1.

### Protease Digestion

- Transfer 100 µl (mix first by pipetting up and down at least three times) of each homogenate from the Master Plate to the corresponding well of the Digestion Plate (Appendix II). Afterwards, the Master Plate may be covered and stored for at 5±3°C for up to 8 hours or at -20°C to -80°C for up to 12 months. Mix the samples and the digestion solution by pipetting up and down at least three times.
- Cover the Digestion Plate with a Sealing Film (Component 4).
- Digest for 60±2 min at 47±1°C.
- Stop the reaction by adding 10 µl of Digestion Stop (Component 6). Mix by pipetting up and down at least three times.
- After Digestion Stop has been added the Digestion Plate may be covered with a Sealing Film and stored at -20°C to -80°C for up to 5 days.

## PREINCUBATION

### Preparatory Steps

- Place Assay Buffer (Component 7) at 22±3°C for at least 2 hours prior to use.
- Reconstitute the functional Positive Control (Component 12) by adding first 200 µl water and then 200 µl Assay Buffer (Component 7, green). Mix by vortexing and inverting the tube several times.
- Reconstitute the Negative Control (Component 13) by adding first 200 µl water and then 200 µl Assay Buffer (Component 7, green). Mix by vortexing and inverting the tube several times.
- If required, the functional Positive and Negative Controls can be ordered separately (see "Additional Material Required").

### Preincubation

- Add 150 µl of Assay Buffer (mix thoroughly before use) to the digested homogenate in the Digestion Plate and mix by pipetting up and down at least three times.
- Incubate at 22±3°C for 15±1 min.
- Add first 12 µl of the reconstituted Negative Control to well B1 and then 12 µl of the reconstituted functional Positive Control to well A1 of the Test Plate (Component 8, White Plate, Appendix II).
- Transfer 12 µl of the preincubated sample (mix again by pipetting up and down at least five times) from the Digestion Plate to the Test Plate. Visually control proper transfer (Appendix II).

## DETECTION

### Preparatory Steps

- Reconstitute the lyophilized Conjugate (Component 10) by adding 9 ml Conjugate Buffer (Component 9). Mix immediately by vortexing vigorously for at least 15 sec upon addition of conjugate buffer and just prior to each use.
- Place pouches containing the PrioSTRIP® combs (Component 11) at 22±3°C, at least 30 min prior to opening.

### Detection

- Add 80 µl of the reconstituted Conjugate to each well containing sample or control of the Test

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Plate using a multichannel pipette. Mix by slowly pipetting up and down twice.

- Lower the PrioSTRIP® combs into the sample mixture. Place the combs in the Test Plate such that strip A of the PrioSTRIP® comb is in a well of row A and strip B in a well of row B etc.
- Leave PrioSTRIP® in the wells for 20±1 min at 22±3°C.
- Interpret and scan results within 10 min.

## INTERPRETATION OF RESULTS

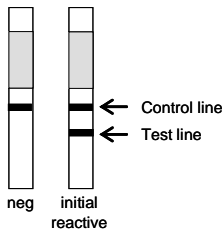
### Visual Interpretation

Visual interpretation requires two people (readers) who individually interpret each result. In all samples the control line must appear.

A PrioSTRIP® Visual Interpretation Sheet is supplied for each PrioSTRIP® Test Plate. Carefully follow the instructions on the Visual Interpretation Sheet.

The sample is:

- **negative** if only the Control line is visible.
- an **initial reactive** if both the Control line and the Test line (1-2 mm below the Control line) are visible.
- **invalid** if no lines or only Test line appears.



The readers then compare their results. Positive and Negative Controls must show a correct result. If not, the entire plate is invalid and has to be retested starting from the corresponding homogenates.

Results:

- All samples found to be an **initial reactive** by one or both readers need to be retested in duplicate starting from their corresponding homogenates. The two outcomes resulting from retesting an initially reactive sample are then individually interpreted by the two readers. The readers compare their results and in case one or both readers interpret the result as positive or invalid, the result needs to be indicated to the National Reference Laboratory. If both readers interpret the result as negative, the sample is negative.
- A sample found to be **invalid** by one or both readers needs to be retested (single) starting from the corresponding homogenate. The outcome resulting from retesting an invalid sample is individually interpreted by the two readers. The two readers compare their results.
  - If both readers interpret the outcome as negative, the sample is negative.
  - If one or both readers interpret the outcome as invalid the sample should be referred to the National Reference Laboratory.
  - If one or both readers interpret the outcome as initial reactive, the sample should be regarded as initial reactive and retested in duplicate starting from the corresponding homogenate.

Additional national guidelines may apply.

### Interpretation with the PrioSCAN®:

The PrioSCAN® converts the blue lines on the strips into digital data. The values obtained with the PrioSCAN® are given as Relative Density Units (RDU). The cutoff is lot dependent and provided with each new lot, encoded on the lot calibration sheet.

The sample is:

- **Negative**, if the value of the test line is below cutoff and the control line is present
- **Initial reactive**, if the value of the test line is above cutoff and the control line is present
- **Invalid**, if no control line is present

If the Negative Control or the functional Positive Control or both do not show the correct result, the plate is invalid and all samples on the plate have to be retested from the corresponding homogenates.

Results:

- All samples found to be **initial reactive** need to be retested in duplicate starting from their corresponding homogenates. In case one or both results are detected as positive or invalid, the result needs to be indicated to the National Reference Laboratory.
- All samples found to be **invalid** need to be retested (single) starting from their corresponding homogenates.
  - If the result is interpreted as negative the sample is negative.
  - If the result is interpreted as invalid the result needs to be indicated to the National Reference Laboratory (NRL).
  - If the result is interpreted as initial reactive, the sample should be regarded as initial reactive and retested in duplicate starting from the corresponding homogenate.

Additional national guidelines may apply.

### For visual and automated interpretation:

Samples and the corresponding tissue giving positive or invalid rapid test results should be sent to the NRL for confirmation.

If visual interpretation is used, laboratories testing under EU Regulation 999/2001 must create legible records of all combs (for example electronically by scanning or taking a digital photo).

## General Remarks

### Notice

This manual is believed to be complete and accurate at the time of publication. In no event shall Prionics AG be liable for incidental or consequential damage in connection with or arising from the use of this manual.

### Liability

Prionics AG warrants its products will meet their applicable published specification when used in accordance with their applicable instructions and within the declared products life time. Prionics AG makes no other warranty, expressed or implied. There is no warranty of merchantability or fitness for a particular purpose. The warranty provided herein and the data, specifications and descriptions of Prionics AG products appearing in Prionics AG published catalogues and product literature may not be altered except by express written agreement signed by an officer of Prionics AG. Representation, oral or written, which are inconsistent with this warranty or such publications are not authorized and if given, should not be relied upon.

In the event of a breach of the foregoing warranty, Prionics AG's sole obligation shall be to repair or replace, at its option, the applicable product or part thereof, provided the customer notifies Prionics AG promptly of any such breach. If after exercising reasonable efforts, Prionics AG is unable to repair or replace the product or part, then Prionics AG shall refund to the customer all monies paid for such applicable product or part.

Prionics AG shall not be liable for consequential, incidental, special or any other indirect damages resulting from economic loss or property damage sustained by any customer from the use of its products.

Prionics AG is an ISO 9001:2000 certified company.

## Appendix I

### Table for preparation of homogenization working solution and digestion solution

#### Homogenization working solution

Mix indicated volumes of purified water and 5x Homogenization Buffer (Component 1) to obtain the desired volume of homogenization working solution: Shelf life of homogenization working solution: 1 week at 5±3°C.

Vol. of Homogenization working solution	=	Volume of Homogenization Buffer (5x) (Component 1)	+	Volume of purified water
250 ml	=	50 ml	+	200 ml
500 ml	=	100 ml	+	400 ml
1000 ml	=	200 ml	+	800 ml
1500 ml	=	300 ml	+	1200 ml

#### Digestion solution

Mix indicated volumes of homogenization working solution, Digestion Buffer (Component 2) and Proteinase K (Component 5) (in this sequence) in a single-use plastic tube (e.g., 15 ml reaction tube) just prior to use. Shelf life of digestion solution: 15 min at 22±3°C.

No. of plates	Vol. of digestion solution	=	Vol. of homogenization working solution	+	Vol. of Digestion Buffer (Component 2)	+	Vol. of Proteinase K (Component 5)
1	6 ml	=	3.6 ml	+	1.2 ml	+	1.2 ml
2	12 ml	=	7.2 ml	+	2.4 ml	+	2.4 ml
3	18 ml	=	10.8 ml	+	3.6 ml	+	3.6 ml
4	24 ml	=	14.4 ml	+	4.8 ml	+	4.8 ml
5	30 ml	=	18 ml	+	6 ml	+	6 ml

## Appendix II

### Pipetting Schemes

Recommended pipetting scheme for **Master Plate** and **Digestion Plate** (Component 3, Colourless Plate)

	1	2	3	4	5	6	7	8	9	10	11	12
A	Sample 7	Sample 15	Sample 23	Sample 31	Sample 39	Sample 47	Sample 55	Sample 63	Sample 71	Sample 79	Sample 87	Sample 95
B	Sample 8	Sample 16	Sample 24	Sample 32	Sample 40	Sample 48	Sample 56	Sample 64	Sample 72	Sample 80	Sample 88	Sample 96
C	Sample 1	Sample 9	Sample 17	Sample 25	Sample 33	Sample 41	Sample 49	Sample 57	Sample 65	Sample 73	Sample 81	Sample 89
D	Sample 2	Sample 10	Sample 18	Sample 26	Sample 34	Sample 42	Sample 50	Sample 58	Sample 66	Sample 74	Sample 82	Sample 90
E	Sample 3	Sample 11	Sample 19	Sample 27	Sample 35	Sample 43	Sample 51	Sample 59	Sample 67	Sample 75	Sample 83	Sample 91
F	Sample 4	Sample 12	Sample 20	Sample 28	Sample 36	Sample 44	Sample 52	Sample 60	Sample 68	Sample 76	Sample 84	Sample 92
G	Sample 5	Sample 13	Sample 21	Sample 29	Sample 37	Sample 45	Sample 53	Sample 61	Sample 69	Sample 77	Sample 85	Sample 93
H	Sample 6	Sample 14	Sample 22	Sample 30	Sample 38	Sample 46	Sample 54	Sample 62	Sample 70	Sample 78	Sample 86	Sample 94

Recommended pipetting scheme **Test Plate** (Component 8, White Plate)

	1	2	3	4	5	6	7	8	9	10	11	12
A	+	Sample 7	Sample 15	Sample 23	Sample 31	Sample 39	Sample 47	Sample 55	Sample 63	Sample 71	Sample 79	Sample 87
B	-	Sample 8	Sample 16	Sample 24	Sample 32	Sample 40	Sample 48	Sample 56	Sample 64	Sample 72	Sample 80	Sample 88
C	Sample 1	Sample 9	Sample 17	Sample 25	Sample 33	Sample 41	Sample 49	Sample 57	Sample 65	Sample 73	Sample 81	Sample 89
D	Sample 2	Sample 10	Sample 18	Sample 26	Sample 34	Sample 42	Sample 50	Sample 58	Sample 66	Sample 74	Sample 82	Sample 90
E	Sample 3	Sample 11	Sample 19	Sample 27	Sample 35	Sample 43	Sample 51	Sample 59	Sample 67	Sample 75	Sample 83	Sample 91
F	Sample 4	Sample 12	Sample 20	Sample 28	Sample 36	Sample 44	Sample 52	Sample 60	Sample 68	Sample 76	Sample 84	Sample 92
G	Sample 5	Sample 13	Sample 21	Sample 29	Sample 37	Sample 45	Sample 53	Sample 61	Sample 69	Sample 77	Sample 85	Sample 93
H	Sample 6	Sample 14	Sample 22	Sample 30	Sample 38	Sample 46	Sample 54	Sample 62	Sample 70	Sample 78	Sample 86	Sample 94

+ Positive Control; - Negative Control

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## Appendix III

### PrioCLIP™/Prypcon Wash Protocol

#### General instructions

##### Sample traceability:

PrioCLIP™/Prypcon homogenization containers must be labeled with sample number – using e.g. a water-proof pen or labels – to guarantee the sample traceability. Labeling of the containers can only be removed after release of results.

##### PrioCLIP™/Prypcon usage traceability:

Homogenization containers should not be used more than 5 times. PrioCLIP™/Prypcon have to be labeled with dashes or dots using a waterproof pen after each use.

#### Do not use hypochlorite-containing disinfectants for washing.

#### Preparatory Steps

- Fill two vessels with sufficient amounts of de-ionized water (at least 25 l) in order to allow complete submersion of the PrioCLIP™/Prypcon during the washing steps.

#### Draining

- Empty containers with homogenates tested "TSE negative" into an autoclavable, heat-resistant bottle or a disposable canister/flask.
- Containers whose contents have been identified "initial reactive" must not be re-used and have to be disposed of according to the national safety guidelines.

#### Washing

- Immerse the empty PrioCLIP™/Prypcon in a vessel with de-ionized water, rinse thoroughly.
- Inspect the homogenization containers visually for possible damage and tissue contamination during transfer from vessel one to vessel two. Discard any damaged or contaminated PrioCLIP™/Prypcon homogenization containers.
- Submerge containers and incubate at least 30 min at 22±3°C.

#### Drying

- Take the PrioCLIP™/Prypcon out of the vessel, shake out remaining water and let them dry completely at 22±3°C.
- Alternatively, PrioCLIP™/Prypcon can be dried in a heating/ drying oven. Place the containers on a heat-resistant surface, heat them for 2 hrs at 85±5°C and dry over night at 50°C in a drying oven. Repeat heating step (2 hrs, 85±5°C).
- Visually check PrioCLIP™/Prypcon. Discard containers that are damaged or contain remaining fluid or tissue.
- Now PrioCLIP™/Prypcon are ready for re-use.

#### Waste disposal

- Homogenates and washing solutions have to be disposed of according to national safety guidelines.

A detailed PrioCLIP™/Prypcon wash protocol (including pictures) can be requested at [info@prionics.com](mailto:info@prionics.com)

## Appendix IV

### Safety Regulations and R&S Statements

#### Safety Regulations

##### 1. National Safety Regulations must be strictly followed.

##### 2. ACDP guidelines

Laboratories MUST adhere to National Safety Regulations, but the following information – published by the Advisory Committee on Dangerous Pathogens (ACDP) – is available for guidance: "Transmissible spongiform encephalopathy agents: safe working and the prevention of infection", Department of Health, London, UK (can be ordered at the Stationery Office, ISBN

0113221665, phone number +44 (20) 7873 9090). An update is available under [www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/CJD/CJDGeneralInformation/fs/en](http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/CJD/CJDGeneralInformation/fs/en)

#### 3. Symbols and codes used



Used to indicate the expiry date



Used to indicate the storage conditions

#### R&S Statements

##### Component 1

##### Homogenization Buffer (5x)

Hazard Code: This product is not classified according to EU regulations.

##### Component 2

##### Digestion Buffer

Hazard Code: R22 Harmful if swallowed.

R36/38 Irritating to eyes and skin.

S23 Do not breathe gas/fumes/vapour/spray.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S35 This material and its container must be disposed of in a safe way.

S36/37 Wear suitable protective clothing and gloves.

##### Component 3

##### Digestion Plates (Colorless Plates)

Hazard Code: This product is not classified according to EU regulations.

##### Component 4

##### Sealing Film

Hazard Code: This product is not classified according to EU regulations.

##### Component 5

##### Proteinase K

Hazard Code: This product is not classified according to EU regulations.

##### Component 6

##### Digestion Stop

Hazard Code: This product is not classified according to EU regulations.

##### Component 7

##### Assay Buffer

Hazard Code: R22 Harmful if swallowed.

R36/38 Irritating to eyes and skin.

S23 Do not breathe gas/fumes/vapour/spray.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S35 This material and its container must be disposed of in a safe way.

S36/37 Wear suitable protective clothing and gloves.

##### Component 8

##### Test Plate (White Plates)

Hazard Code: This product is not classified according to EU regulations.

##### Component 9

##### Conjugate Buffer

Hazard Code: This product is not classified according to EU regulations.

##### Component 10

##### Conjugate

Hazard Code: This product is not classified according to EU regulations.

##### Component 11

##### PrioSTRIP® Combs

Hazard Code: This product is not classified according to EU regulations.

##### Component 12

##### Positive Control

Hazard Code: This product is not classified according to EU regulations.

#### Component 13

##### Negative Control

Hazard Code: This product is not classified according to EU regulations.

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