Medical devices

BIOplastics BV manufacturer consumables serving the molecular biology market, in particular the (q)PCR and molecular diagnostics marketplace.
BIOplastics offers the widest and most superior range (q)PCR plastics whereas this plastic consumables and labware are superior in quality, reproducibility of results.

Product description:

(q)PCR products
0.1 ml & 0.2 ml thin wall tubes, strips and plates and closure caps to perform
(Real Time) DNA amplification and detection.

GRADIENT FILTERTIPS and pipette tips
Gradient filtertips provide protection against aerosols that could contaminate pipettes, cross-contaminate samples, and contaminate reaction set ups. The protection is given by the 18 µm gradient Self Sealing pores.
Pipette Tips are used to transfer a designated volume from one vessel to another. BIOplastics pipette tips are optimized to be used with DNA and Salt containing liquids.

Incubation, transfer and storing Tubes
Tubes are used to prepare and perform reactions, and to store the final reaction product. Tubes are high quality, durable, consistent and stable. BIOplastics tubes are manufactured under strict quality controlled conditions and the design ensures smooth inner surfaces, easy closure and reproducible results. The tubes can be frozen down to -200 ℃ and heated up t o 100 ℃ , be centrifuged up to 20.000 g and are optimized to be used with DNA and Salt and or DNA/RNA containing liquids.

Racks and Storage
Designed to store BIOplastics tubes, plates which improve sample archivation and which have a working range of frozen down to -200 ℃ and heated up to 1 00 ℃.

Criteria used for Quality control:

	Depending of type of product
(q)PCR products	DNA (absent of)
	DNAse (absent of)
	RNAse (absent of)
	Pyrogen (absent of)
	Leakage(1)
	Flash
	Air entrapment
	Breakage
	Cosmetics
	Evaporation
GRADIENT FILTERTIPS and pipette tips	
	DNA (absent of)
	DNAse
	RNAse
	Pyrogen (absent of)
	Flash
	Air entrapment
	Cosmetics
	Liquid recovery
Incubation, transfer and storing Tubes	
	DNA (absent of)
	DNAse
	RNAse
	Pyrogen (absent of)
	Leakage (2)
	Flash
	Air entrapment
	Breakage
	Cosmetics
Racks and Storage	
	Flash
	Air entrapment
	Cosmetics

Name of medical devices and/or products
(q)PCR vessel products
GRADIENT FILTERTIPS and pipette tips
Incubation, transfer and storing Tubes
Racks and Storage Racks

indicator	description	specifications Method
1	DNA (absent of)	PCR amplification
2	DNAse (absent of)	DNA incubation and gel-electroforesis
3	RNAse (absent of)	tRNA incubation and gel-electroforesis
4	Pyrogen (absent of)	LAL Gel cloth
5	Leakage(1)	Air pressure Vacuum method
6	Flash	Visual-Caliper
7	Air entrapment	Visual-Caliper
8	Breakage	Counting/gravimetric
9	Cosmetics	Visual-Caliper
10	Evaporation	Gravimetric PCR cycling
11	Liquid recovery	Gravimetric Liquid recovery TBE
12	Leakage(2)	Methanol storage

Specification

Indicators	Methods
1	
DNA absent	PCR amplification

DETECTION OF DNA IN INJECTION MOULDED PRODUCTS
The absence of DNA in injection molded products is tested by washing the products with Nuclease free water and perform a PCR amplification with specific primers on the samples as well as positive and negative controls.
After amplification, gel-electrophoresis and staining the gel is checked for the absence of DNA in samples and negative control.

SCOPE

This document describes the required handlings for testing the absence of DNA in injection molded products with PCR amplification method and specific primers.

1.0 ***REQUIRED MATERIALS***

1.1 Products to be tested delivered by packaging department
1.2 Pipette set
1.3 Premixed dNTP solution
Taq DNA polymerase
MgCl2 solution
10x PCR buffer
dNTP Mix
L1-5' primer TGT – GGA – AGT – CAC – TGT – GGC - GA
L1-3' Primer CCA – ATT – TCA – TCC – ATG – TCC - CT
Human DNA
Agarose
Ethidium bromide
TBE buffer
2kb DNA Ladder (in EDTA, Glycerol and Bromephenol Blue)
Nuclease free water

2.0 ***REQUIRED EQUIPMENT***

2.1 Thermocycler
2.2 Vortex
2.3 Safety glasses
2.4 Latex gloves
2.5 Miscellaneous

3.0 ***PROCEDURE***

3.1 Sample preparation

3.1.1 *qPCR plates, tubes en strips*
Pipette 150 µl Nuclease Free Water in first tube and transfer 150 µl from this tube over to a second tube. Transport for maximal 30 times to different tubes, so test a maximum of 30 different products and/or different wells.

3.1.2 *qPCR 384 plates*
Pipette 25 µl Nuclease Free Water in first well and transfer 25 µl from this well over to a second well. Transport for maximal 30 times to different wells, so test a maximum of 30 different products and/or different wells.

3.1.3 *qPCR strip-caps, cap-plates, screw-caps*
Pipette 150 µl Nuclease Free Water in a test tube and strip. Place caps, vortex for 2 seconds and tap off or centrifuge. The solution has to be at the bottom of the tube. Remove the cap and place the next to be tested cap. Place maximal 30 different caps, so test a maximum of 30 different products and/or different cap wells.

3.1.4 *Micro centrifuge tubes 0.5 ml, 1.5 ml, 2 ml, screw cap tubes and titer tubes*
Pipette 500 ul Nuclease Free water in first vial and transfer 500 µl from this vial to a second. Transport maximal 30 times, so test a maximum of 30 different products.

3.1.5 *Pipette tips en filtertips*
Pipette 500 µl Nuclease Free Water in a 2.0 ml reaction tube.
Pipette the maximal capacity of the (filter) tips by pipetting “up-and-down”. Remove the pipette tip and repeat the procedure with a new pipette tip maximal 30 times, so test a maximum of 30 different products.

3.1.6 Mastermix composition (25 µl)
5 µl Taq 10X PCR buffer (1X final concentration)
5 µl MgCl2 25 mM
4 µl dNTP mix 2.5 mM (200 uM final concentration)
1.0 µl Primer L1-3 20 uM (0.4 uM final concentration)
1.0 µl Primer L1-5 20 uM (0.4 uM final concentration)
9 µl Nuclease free water

3.2

Positive control :
24.75 µl Mastermix
0.25 µl Taq DNA polymerase (1.25 Units)
25 µl DNA template (minimal 10 fg)

Negative control :
24.75 µl Mastermix
0.25 µl Taq DNA polymerase (1.25 Units)
25 µl Nuclease free water

Samples :
Preparation

24.75 µl Mastermix
0.25 µl Taq DNA polymerase (1.25 Units)
25 µl Sample Preparation Solution (= to be tested sample)

Then amplify the controls and samples in a thermocycler, 40 cycli (see program)

3.3 Analysis and detection
Program Thermocycler : (ISO 17025 Calibrated)
5 min pre denaturation at 93 C
30 sec denaturation at 94 ºC
45 sec annealing at 60 ºC
45 sec extension at 72 ºC

Detection
Prepare a 1.5 % Agarose gel and pour the gel (<80 ºC) in the electrophoresis chamber en place comb.

Mix the to be tested samples with loading Dye. (3 x = 1:3 and 6 x = 1:6)

Start al following: 12 µl
Lane 1 : ladder
2 : neg. control
3 : pos. control
4 : samples
5 : etc.

Start electrophoresis, 120 V, for 1 hour

3.4 Gel staining (Ethidium bromide)
Place gel and tray in staining camber.
Prepare 100 ml fresh EtBr solution (0.5 µg/ml), pour in the chamber and stain for a period of 1 hour.

3.5 Gel documentation
Place stained gel on the UV trans-illuminator and make a photograph of the illuminated bands.

3.6 Result
The test samples and the negative control should and must show no bands. The positive control should and must show a band at 300 bp (compare with DNA ladder). Presence of band(s) in samples or negative control is indicating Human DNA presence and so DNA contaminated products.

Specification

Indicators	Methods
2	
DNAse absent	DNA incubation and gel-electrophoresis

DETECTION OF DNAse IN INJECTION MOLDED PRODUCTS

The absence of DNAse in injection molded products is tested by washing the products with nuclease free water.
After incubation with DNA, gel-electrophoresis is performed. After staining, the gel is evaluated on the absence of DNAse in samples and negative control.

SCOPE

This document describes the required handlings for testing the absence of DNAse I of injection molded products .

1.0 REQUIRED MATERIALS

1.1 To be tested injection molded products
1.2 pBR322 DNA
Agarose
Ethidium bromide
DNAse I , (RNAse free)
Nuclease free water
MgCl2 25 mM
Loading dye
10 x TBE buffer
2kb DNA Ladder (in EDTA, Glycerol and Bromophenol Blue) (e.g. Norgen, Canada)

2.0 REQUIRED EQUIPMENT

2.1 Incubation oven (37℃)
2.2 Pipette set
2.3 Electrophoresis Gel Chamber
2.4 Power supply electrophoresis
2.5 UV light (flatbed)
2.6 Safety glasses
2.7 Latex gloves
2.8 Miscellaneous

3.0 PROCEDURE

3.1 Sample preparation

3.1.1 *qPCR plates, tubes en strips*
Pipette 150 µl Nuclease Free Water in first tube and transfer 150 µl from this tube over to a second tube. Transport for maximal 30 times to different tubes, so test a maximum of 30 different products and/or different wells.

3.1.2 *qPCR 384 plates*
Pipette 25 µl Nuclease Free Water in first well and transfer 25 µl from this well over to a second well. Transport for maximal 30 times to different wells, so test a maximum of 30 different products and/or different wells.

3.1.3 *qPCR strip-caps, cap-plates, screw-caps*
Pipette 150 µl Nuclease Free Water in a test tube and strip. Place caps, vortex for 2 seconds and tap off or centrifuge. The solution has to be at the bottom of the tube. Remove the cap and place the next to be tested cap. Place maximal 30 different caps, so test a maximum of 30 different products and/or different cap wells.

3.1.4 *Micro centrifuge tubes 0.5 ml, 1.5 ml, 2 ml, screw cap tubes and titer tubes*
Pipette 500 ul Nuclease Free water in first vial and transfer 500 µl from this vial to a second. Transport maximal 30 times, so test a maximum of 30 different products.

3.1.5 *Pipette tips en filtertips*
Pipette 500 µl Nuclease Free Water in a 2.0 ml reaction tube.
Pipette the maximal capacity of the (filter) tips by pipetting “up-and-down”. Remove the pipette tip and repeat the procedure with a new pipette tip maximal 30 times, so test a maximum of 30 different products.

3.2 Test protocol

Pipette as following:
25 µl sample
8 µl MgCl2 25 mM
10 µl DNA 2 Kb (0.1 µg/µl)

Neg control
Pipette as following:
25 µl Nuclease free water
8 µl MgCl2 25 mM
10 µl DNA 2 Kb (0.1 µg/µl)

Pos controls: (3 in total)
25 µl Nuclease free water
8 µl MgCl2 25 mM
10 µl DNA 2 Kb (0.1 µg/µl)
Add DNAse I seq.
Pos Tube 1: 3.3 mU DNAse I (3.3 µl)
Pos tube 2: 5 mU DNAse I (5 µl)
Pos tube 3: 10 mU DNAse I (10 µl)

After pipetting, place in the oven at 37 C for 2 hours.

Detection limit= 3.3 mU DNAse

3.3 Analysis and detection

Prepare a 1.5 % Agarose and place comb.
Place the gel tray in the correct position of the gel chamber.
Mix the to be tested samples with loading Dye. (3 x = 1:3 and 6 x = 1:6)
The end volume of the mix is 15 µl.
Mix thoroughly by pipetting “up-and-down” several times.
Transfer 12 ul sample in the different gel slots

Pipette order
Start as follows: : 12 µl
Lane 1 : ladder
2 : neg. control
3 : pos. control 1
4 : pos. control 2
5 : pos. control 3
6 : samples
7 : etc

Set Power supply in for 120 V ,1 hour.

3.4 Gel staining (Ethidium bromide)
Place gel and tray in staining camber.
Prepare fresh EtBr solution (0.5 µg/ml) and pour 100 ml EtBr in the chamber and stain for a period of 1 hour

3.5 Gel documentation
Place colored gel on the UV transilluminator
Make a photograph of the illuminated bands

3.6 Result
The test samples and the negative control should show no degradation (no smear). The positive controls should be smeared as a result of DNAse contamination.

Specification

Indicators	Methods
3	
RNase absent	tRNA incubation and gel-electrophoresis

DETECTION OF RNAse IN INJECTION MOLDED PRODUCTS

The absence of RNAse in injection molded products is tested by washing the products with nuclease free water.
After incubation with tRNA, gel-electrophoresis is performed. After staining, the gel is evaluated for the absence of RNAse in samples and negative control.

SCOPE

This document describes the required handlings for testing the absence of RNAse of injection molded products.

1.0 REQUIRED MATERIALS

1.1 To be tested injection molded products, delivered by packaging department
1.2 Resolute agarose
1.3 Ethidium bromide
1.4 RNase A (e.g. Epibio MRNA092)
1.5 tRNA (e.g. Sigma R1753-500UN)
1.6 Nuclease free water
1.7 Loading Dye
1.8 10 x TBE buffer
1.9 10 kb DNA ladder (in EDTA, Glycerol and Bromophenol blue)

2.0 REQUIRED EQUIPMENT

2.1 Incubation oven (37C)
2.2 Pipette set
2.3 Electrophoresis Gel Chamber
2.4 Power supply electrophoresis
2.5 UV light (flatbed)
2.6 Safety glasses
2.7 Latex gloves
2.8 Miscellaneous
2.9 Gel loading tips

3.0 PROCEDURE

3.1 Sample preparation

3.1.1 qPCR plates, tubes en strips
Pipette 150 µl Nuclease Free Water in first tube and transfer 150 µl from this tube over to a second tube. Transport for maximal 30 times to different tubes, so test a maximum of 30 different products and/or different wells.

3.1.2 qPCR 384 plates
Pipette 25 µl Nuclease Free Water in first well and transfer 25 µl from this well over to a second well. Transport for maximal 30 times to different wells, so test a maximum of 30 different products and/or different wells. Last amount is transported to new tubes with 125 µl Nuclease free water

3.1.3

3.1.4 *qPCR strip-caps, cap-plates, screw-caps*
Pipette 150 µl Nuclease Free Water in a test tube and strip. Place caps, vortex for 2 seconds and tap off or centrifuge. The solution has to be at the bottom of the tube. Remove the cap and place the next to be tested cap. Place maximal 30 different caps, so test a maximum of 30 different products and/or different cap wells.

3.1.5 *Micro centrifuge tubes 0.5 ml, 1.5 ml, 2 ml, screw cap tubes and titer tubes*
Pipette 500 ul Nuclease Free water in first vial and transfer 500 µl from this vial to a second. Transport maximal 30 times, so test a maximum of 30 different products.

3.1.6 *Pipette tips en filtertips*
Pipette 500 µl Nuclease Free Water in a 2.0 ml reaction tube.
Pipette the maximal capacity of the (filter) tips by pipetting "up-and-down". Remove the pipette tip and repeat the procedure with a new pipette tip maximal 30 times, so test a maximum of 30 different products.

3.2 Test protocol

Pipette as following:
45 µl sample
5 µl tRNA (1 µg/µl)

Neg. control
Pipette as following:
45 µl Nuclease free water (EPI)
5 µl tRNA (1 µg/µl)

Pos control
44 µl Nuclease free water (EPI)
5 µl tRNA (1µg/µl)
1 µl RNAse A (0.5 mU)

After pipetting, place in the oven at 37ºC for 2 hours

Detection limit = 0.3 mU RNAse

3.3 Analysis and detection

Prepare a 1.0 % agarose gel , pour the gel (<80 ºC) in the electrophoresis chamber en place comb

Mix the samples with loading Dye. (3 x = 1:3 and 6 x = 1:6)

Pipette order
Start as following: 15 µl
Lane 1 : ladder
2 : neg. control
3 : pos. control
4 : samples
5 : etc

Set Power supply in for 120 V ,1 hour.

Gel staining (ethidium bromide)
Place gel and tray in staining camber.
Prepare fresh EtBr solution (0.5 µg/ml) and pour 100 ml EtBr solution in the chamber and stain for a period of 1 hour.

3.4 Gel documentation
Place colored gel on the UV transilluminator
Make a photograph of the illuminated bands.

3.5 Result
The test samples and the negative control should show no degradation. The positive control should be smeared as a result of the effect of RNase contamination of the tRNA that is used in all the reactions.

Specification

Indicators	Methods
4	
Pyrogen Detection	LAL Gel cloth Method

Detection of pyrogens in injection molded products

The absence of pyrogens in injection molded products is tested by washing the products with endotoxine free water.
After adding LAL Lysate, the positive and negative control and samples are incubated for 1 hour at 37 C.
A positive reaction is characterized by the formation of a firm gel.
A negative reaction is characterized by the absence of a solid clot.

SCOPE

This document describes the required handlings for testing the absence of pyrogens in injection molded products by the LAL method (Lumulus Amoebocyte Lysate)

1.0 REQUIRED MATERIALS

1.1 LAL Lysate
LAL Reagent water
Endotoxine standard
NaOH 0.1 N
HCl 0.1 N

2.0 REQUIRED EQUIPMENT

2.1 Incubator 37 ºC
2.2 Test tube rack
2.3 Vortex
2.4 Latex gloves
2.5 Endotoxine free pipettips 200 µl
2.6 Endotoxine free pipettips 1000µl
2.7 Endotoxine free tubes
2.8 Incubation rack

3.0 PROCEDURE

3.1 Sample preparation

3.1.1 *qPCR plates, tubes en strips*
Pipette 150 µl Nuclease Free Water in first tube and transfer 150 µl from this tube over to a second tube. Transport for maximal 30 times to different tubes, so test a maximum of 30 different products and/or different wells.

3.1.2 *qPCR 384 plates*
Pipette 25 µl Nuclease Free Water in first well and transfer 25 µl from this well over to a second well. Transport for maximal 30 times to different wells, so test a maximum of 30 different products and/or different wells.

3.1.3 *qPCR strip-caps, cap-plates, screw-caps*
Pipette 150 µl Nuclease Free Water in a test tube and strip. Place caps, vortex for 2 seconds and tap off or centrifuge. The solution has to be at the bottom of the tube. Remove the cap and place the next to be tested cap. Place maximal 30 different caps, so test a maximum of 30 different products and/or different cap wells.

3.1.4 *Micro centrifuge tubes 0.5 ml, 1.5 ml, 2 ml, screw cap tubes and titer tubes*
Pipette 500 ul Nuclease Free water in first vial and transfer 500 µl from this vial to a second. Transport maximal 30 times, so test a maximum of 30 different products.

3.1.5 *Pipette tips en filtertips*
Pipette 500 µl Nuclease Free Water in a 2.0 ml reaction tube.
Pipette the maximal capacity of the (filter) tips by pipetting “up-and-down”. Remove the pipette tip and repeat the procedure with a new pipette tip maximal 30 times, so test a maximum of 30 different products.

3.2 Test protocol

3.2.1 *Preparing reagent*
Solve the lyophilized Lysate by adding 2 ml LAL Reagent water.

Positive control
Solve E.Coli endotoxine Standard by adding 1 ml LAL reagent water. Concentration is 0.5 EU/ml

Negative control
LAL Reagent water

3.2.2 *Test procedure*

Pipette carefully 0.1 ml LAL reagent and 0.1 ml control or sample in a endotoxine free vial.
Cap the vials and mix thoroughly.
Incubate the controls and samples for 1 hour at 37 ºC
Remove the incubation rack after 1 hour incubation.
Do not shake vigorously while checking, it will break up gel consistency

3.3 Detection

A positive reaction is characterized by the formation of a firm gel.
A negative reaction is characterized by the absence of a solid clot.

Specification

Indicators	Methods
5	
Leakage(1)	Air Pressure vacuum method

Leakage test 1 injection molded products

Leakage of injection molded products is tested by applying air pressure to selected products when submerged into water. No are bubbles should occur.
A positive reaction is characterized by the formation air bubbles.
A negative reaction is characterized the formation air bubbles.

SCOPE

This document describes the required handling for testing the absence of wholes holes in Injection molded products, also called primary leaketest1

1 REQUIRED MATERIALS

1.1 Tested products
1.2 Air pressure minimal of 75 PSI

2 REQUIRED EQUIPMENT

2.1 A single tubing with a diameter slightly smaller that the chimney of the tubes/well to be tested.
The tubing is connected to air pressure (75 psi) whereas the air pressure is controlled by an adjustable valve or a pressure unit with sleeves and column pressure guide equipment tools allows multiple channel testing.

2.2 Pressured air, reducible with valve, to 75 PSI

3 PROCEDURE

3.1 Samples applicable
qPCR plates, tubes en strips as also 0.25 0.5, 1.5 and 2.0 ml tubes

Test protocol

Position either specific pressure tool or tubing in product; submerge product part into water container and open air pressure valve.
Check the appearance of air bubbles.

Detection
No air bubbles: pass
Air bubbles visual: fail

Specification

Indicators	Methods
6	
Flash (membrane formation)	Visual Caliper

Flash determination in injection molded products

Flash in products are determined and measured. Although Flash appearance is mostly a cosmetic issue too much flash is not accepted.

SCOPE

This document describes the required handlings for testing the amount of flash appearance

REQUIRED EQUIPMENT
Caliper, minimal resolution 0.01 mm
magnifier (10X)

Products

qPCR plates, tubes en strips
qPCR strip-caps, cap-plates
Micro centrifuge tubes 0.5 ml, 1.5 ml, 2 ml, screw cap tubes and titer tubes
rack

Test protocol
Examine products for flash. Make a difference between functional part and non functional part of the product.

Detection: If Flash is visual make notice and measure flash dimension with caliper.
On non functional parts the flash should be less than 1 mm.
On functional parts the flash should be less than 0.4 mm.

Specification

Indicators	Methods
7	
Air entrapment	Visual Caliper

Air entrapment determination in injection molded products

Air entrapment in products are determined and measured. Although air entrapment appearance is a cosmetic issue too much air entrapment is not accepted.

SCOPE

This document describes the required handlings for testing amount of air entrapment appearance

REQUIRED EQUIPMENT

Caliper with minimal resolution 0.01 mm
Magnifier (10X)

PRODUCTS

qPCR plates, tubes en strips
qPCR strip-caps, cap-plates
Micro centrifuge tubes 0.5 ml, 1.5 ml, 2 ml, screw cap tubes and titer tubes rack

TESTPROTOCOL

Examine products for air entrapment. Make a difference between functional and non functional parts. Functional parts are parts defined as absolute required for its functionality. (e.g. caps closure, angle part of tube in PCR tubes (heat- transfer)
Non functional parts are e.g. the connections surface in a PCR plate, so tube to tube connection)

DETECTION

If air entrapment is visual make notice and measure air entrapment dimension.
On non functional parts the entrapped air should be less than 5 square mm
On functional parts the entrapped air should be less than 1 square mm

Specification

Indicators	Methods
8	
Breakage	Counting

Breakage determination in injection molded products

Amount of products, not attached to each other are determined and measured. Although non attached products (“broken products”) are fully functional the appearance in bags should be very low to non existing. Certain “fragile” products are sensitive for breakage during manufacturing and packaging.

SCOPE

This document describes the required handlings for testing amount of non attached products (“broken products”)

Products

qPCR tubes en strips
qPCR strip-caps, cap-plates

Test protocol
Examine visually and count non attached products (“broken products”)

Calculation :
Total non attached products x 100 % = % breakage
Total products

Detection: non attached products (“broken products”) is visual make notice and calculate % of it.
Non attached products (“broken products”) should be less as 1% in final product.

Specification

Indicators	Methods
9	
Cosmetic	Visual caliper

Cosmetic “pin” determination in injection molded products

Injection molded products can have injection pins. The appearance pins, sometime not avoidable, should be within accepted criteria.

SCOPE

This document describes the required handling for testing amount and length of injection pins

1 REQUIRED EQUIPMENT
Caliper with minimal resolution 0.01 mm

Products *All products*

Test protocol
Examine products for injection pins and when occur measure length of it.

Detection: If pins available the length should never exceed 1.8 mm.

Specification

Indicators	Methods
10	
Evaporation	PCR cycling Gravimetric

Evaporation determination in qPCR products

SCOPE

This document describes the required handling for determine evaporation rates of qPCR vessels and plates

1 REQUIRED EQUIPMENT

High accuracy Balance (0.0000 g)
Pipette
PCR Cycler

2 PRODUCTS

0.1 and 0,2 ml (q)PCR tubes, strip-tubes and plates

3 TEST PROTOCOL

Pipette X µl distillated water in each well of the tested product. Cap the products with the appropriate BIOplastics caps. Measure the weight of each product. Position products in a thermal cycler. Close lid and Incubate for 1 hour at 99.9 C with lid closed and programmed at 105C. After run remove tested products from cycler and weigh again. Calculate the % evaporation of each product.

Calculation :

(Weight before in g – weight after in g) * 1000 = difference in µg.

$$\frac{\text{Difference in µg}}{\text{Total pipette water volume in µl (µg)}} \times = \% \text{ evaporation.}$$

Detection: Evaporation should be less than 10% (=pass) and preferably less then 5%

Specification

Indicators	Methods
11	
Liquid recovery	Gravimetric liquid recovery TBE

Liquid recovery in BIOplastics Pipettips

SCOPE

This document describes the required handling for determine liquid recovery for BIOplastics Pipettips

1 REQUIRED EQUIPMENT
High accuracy Balance (0.0000 g)
Pipettes
10X TBE buffer (National Diagnostics)

Products *All BIOplastics Pipettips*

Test protocol
Measure the weight of an empty narrow vessel (A) on your balance.
Pipette 10 x X ul of TBE buffer into a narrow vessel A.
Measure the weight (B) of vessel A with TBE buffer on your balance and calculate the pipetted net weight.
Specific Gravity TBE 10X = 1.16 g/ml

Calculation:
B (Weight A + TBE) – A (Weight A empty) = weighed volume in µg
Weighed volume in µg x 1.016 x 100 % = % Liquid recovery
Pipetted volume in µl

Detection: For tips <= 10 µl recovery should be 96% or higher
For tips >= 10 µl recovery should be 98.5 % or higher

Specification

Indicators	Methods
12	
Leakage(2)	Methanol storage

Leakage test 2 injection molded products

Leakage of injection molded products is tested by filling products with colored (dye) methanol and store the product for at least 1 week at RT

SCOPE

This document describes the required handling for testing leakage in Injection molded products

1.0 REQUIRED MATERIALS

tested products
Dyed Methanol

2.0 REQUIRED EQUIPMENT
High accuracy Balance (0.0000 g)

3.0 PROCEDURE

Samples applicable
qPCR plates, tubes en strips as also 0.25 0.5, 1.5 and 2.0 ml tubes

Test protocol:
Fill products to the maximum with dyed methanol and close with cap. Measure the weight of the sample. Store sample at room temperature for at least 7 days. After 7 days measure the weight of the sample again and calculate % of recovery.

Calculation : Weight before x 100 % = % recovery
Weight after

Detection
Less than 0.2 % of liquid is allowed to leak or a recovery of more than 99.8% should occur