

RNase Test Data and Results

Date: 12/9/2016
Company: SHIELD Scientific
Date received: 11/22/2016

Project #: 114001A
Contact: Iris Roelofs
Technician: Mireille Wojtanek

PO#: SSE271016
Phone: 0031 317 700202

Products tested:
SHIELDskin™ ORANGE NITRILE™ 300 Sterile glove

Product code:
67 635X

Lot #:
3K151342B

Extraction:

Extract solution: DEPC treated Water
Lot #: DW16119
Volume: 1000µl

Number of test items exposed to extract solution: 10
Special extraction instructions: extracted 10 spots total on 10 gloves

Procedure and Controls:

RNA: 6.0 kb Poly (A)-tailed
RNA lot #: 1407022
Salts: MgCl₂ and NaCl
Salt lot #: S15G2

RNA standard pool: 3µl of RNA + 12µl Salts.
Volume of each standard reaction: 5µl
Volume of extract added to the standard: 10µl
Total volume: 15µl

Negative Control (-): RNA and salt standards with 10 µl of unexposed extract solution added

Positive Control (+): RNA and salt standards with 10 µl of extract solution exposed to RNase from a tip touched by un-gloved hands

Incubation periods: 1 hr @ 37°C, followed by 5 minutes at 65°C

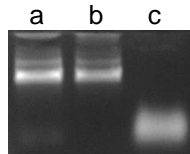
Gel Electrophoresis:

2µl gel loading dye + 15µl reaction is loaded on a 1.2% agarose in ½ X TAE gel

Gel loading dye lot #: D13H7

Electrophoresis: 20 minutes @ 80 volts

Photographic Results:



Lane (a) 67 635X, N/A, (b) unexposed RNA standard as a negative control, (c) RNA standard exposed to RNase as a positive control.

Conclusions:

There is no visible degradation in lanes (a) and (b). Lane (a) represents the product sample and lane (b) represents the negative control. Lane (c), which represents the RNA standard, exposed to RNase as a positive control shows degradation of the RNA. The results suggest that the product sample is free of detectable RNase contamination.

Recommendations:

Based on this experimental procedure, we can show a definite risk of RNase contamination if your product is touched by un-gloved hands. We suggest that all operations are monitored and personnel are instructed in the importance of avoiding RNase contamination.

Mireille Wojtanek
Lab Technician

12/13/2016
Date

Carl Tsang
Q.A.

12/13/2016
Date



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RNase FREE CERTIFICATE OF ANALYSIS

12/13/2016

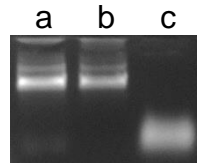
This certifies that the following sample obtained from **SHIELD Scientific** on 11/22/2016 is free of any detectable RNase contamination.

Lots tested:

Product:	Product code:	Lot #:
SHIELDskin™ ORANGE NITRILE™ 300 Sterile glove	67 635X	3K151342B

Product was tested for RNase activity by the following protocol:
Product was extracted in RNase free water. The extract was then added to an RNA standard. The RNA standard was incubated at 37° C for 1 hour then heated to 65° C for 5 minutes. RNA samples were then run on an agarose gel, photographed, and evaluated for degradation.

FIGURE 1.



Lane (a) 67 635X, 3K151342B, (b) unexposed RNA standard as a negative control, (c) RNA standard exposed to RNase as a positive control.

Conclusions:

No visible degradation is present in the product sample. Therefore, the product can be considered RNase free.

Comments:

The Test Sensitivity is 10⁻⁹ Kunitz Units/ µl.



Certified by Mireille Wojtanek, 12/13/2016



Q.A. Carl Tsang, 12/13/2016

DNase Test Data and Results

Date: 12/9/2016
Company: SHIELD Scientific
Date Received: 11/22/2016

Project #: 114001B
Contact: Iris Roelofs
Technician: Mireille Wojtanek

PO#: SSE271016
Phone: 0031 317 700202

Products tested:
SHIELDskin™ ORANGE NITRILE™ 300 Sterile glove

Product code:
67 635X

Lot #:
3K151342B

Extraction:

Extract solution: DEPC treated Water Number of test items exposed to extract solution: 10
Lot #: DW16119 Special extraction instructions: extracted 10 spots total on 10 gloves
Volume: 1000µl

Procedure and Controls:

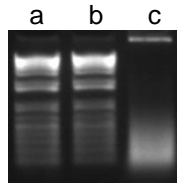
DNA: 1 kb Ladder DNA standard pool: 3µl of DNA + 12µl Salts.
DNA lot #: 1821018 Volume of each standard reaction: 5µl
Salts: MgCl₂ and NaCl Volume of extract added to the standard: 10µl
Salt lot #: S15G2 Total volume: 15µl

Negative Control (-): DNA and salt standards with 10 µl of unexposed extract solution added
Positive Control (+): DNA and salt standards with 10 µl of extract solution exposed to DNase from a tip exposed to human saliva
Incubation periods: 1 hr @ 37°C, followed by 5 minutes at 65°C

Gel Electrophoresis:

2µl gel loading dye + 15µl reaction is loaded on a 1.2% agarose in ½ X TAE gel
Gel loading dye lot #: D13H7 Electrophoresis: 30 minutes @ 80 volts

Photographic Results:



Lane (a) 67 635X, N/A, (b) unexposed DNA standard as a negative control, (c) DNA standard exposed to DNase as a positive control.

Conclusions:

There is no visible degradation in lanes (a) and (b). Lane (a) represents the product sample and lane (b) represents the negative control. Lane (c), which represents the DNA standard, exposed to DNase as a positive control shows degradation of the DNA. The results suggest that the product sample is free of detectable DNase contamination.

Recommendations:

Based on this experimental procedure, we can show a definite risk of DNase contamination if your product is exposed to saliva. We suggest that all operations are monitored and personnel are instructed in the importance of avoiding DNase contamination.



Mireille Wojtanek
Lab Technician

12/13/2016
Date



Carl Tsang
Q.A.

12/13/2016
Date



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DNase FREE CERTIFICATE OF ANALYSIS

12/13/2016

This certifies that the following sample obtained from **SHIELD Scientific** on 11/22/2016 is free of any detectable DNase contamination.

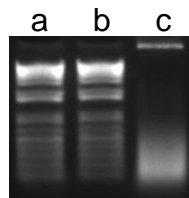
Lots tested:

Product:	Product code:	Lot #:
SHIELDskin™ ORANGE NITRILE™ 300 Sterile glove	67 635X	3K151342B

Product was tested for DNase activity by the following protocol:

Product was extracted in DNase free water. The extract was then added to a DNA standard. The DNA standard was incubated at 37° C for 1 hour then heated to 65° C for 5 minutes. DNA samples were then run on an agarose gel, photographed, and evaluated for degradation.

FIGURE 1.



Lane (a) 67 635X, 3K151342B, (b) unexposed DNA standard as a negative control, (c) DNA standard exposed to DNase as a positive control.

Conclusions:

No visible degradation is present in the product sample. Therefore, the product can be considered DNase free.

Comments:

The Test Sensitivity is 10^{-7} Kunitz Units/ μ l.



Certified by Mireille Wojtanek, 12/13/2016



Q.A. Carl Tsang, 12/13/2016