WOJEWÓDZKA STACJA
SANITARNO - EPIDEMIOLOGICZNA
w Rzeszowie
ul. Wierzbowa 16
35 - 959 Rzeszów

Rzeszów, dnia 23.02.2023 r.

Odpowiedzi na pytania Wykonawcy I

Dotyczy: Zapytania ofertowego „Sukcesywna dostawa odczynników chemicznych i wzorców dla Wojewódzkiej Stacji Sanitarno- Epidemiologicznej w Rzeszowie"

Znak sprawy: OZ.272.1.1.2023.AO

Wojewódzka Stacja Sanitarno- Epidemiologiczna w Rzeszowie, przekazuje odpowiedzi na pytania Wykonawcy, które wpłynęły do Zamawiającego w dniu 21.02.2023 r. i dotyczyły zapisów Zapytania ofertowego i jego załączników:

Pytanie 1

Dotyczy Pakietu nr 7, pozycja 5:

Aflatoksyna M1 Romer Labs nie jest wykonana metodą zgodnie z normą ISO 17034. Czy w związku z tym Zamawiający wyrazi zgodę na zaproponowanie wzorca 10003661, AFLATOXIN M1 - 0.5 µg/mL, 1ml bez akredytacji ISO 17034, zgodnego z załączonym certyfikatem (plik 10003661_1000019171_AFM1.pdf).

Odpowiedź:

Zamawiający wyraża zgodę na zaproponowany wzorzec 10003661, AFLATOXIN M1 - 0.5 µg/mL, 1ml bez akredytacji ISO 17034, zgodny z załączonym certyfikatem

Pytanie 2

Dotyczy Pakietu nr 7, pozycja 7:

Patulina Romer Labs nie jest jeszcze wykonana metodą zgodnie z normą ISO 17034. Czy w związku z tym Zamawiający wyrazi zgodę na zaproponowanie wzorca 0003659 PATULIN - 100 µg/mL, 1 ML bez akredytacji ISO 17034, zgodnego z załączonym certyfikatem (10003659_1000020228_PAT.pdf).

Odpowiedź:

Zamawiający wyraża zgodę na zaproponowany wzorzec 0003659 PATULIN - 100 µg/mL, 1 ML bez akredytacji ISO 17034, zgodny z załączonym certyfikatem

Pytanie 3

Dotyczy Pakietu nr 7:

Czy Zamawiający zaakceptuje certyfikaty w wersji anglojęzycznej dla wszystkich pozycji pakietu, o co bardzo proszę (certyfikaty oferowanych produktów stanowią załącznik do niniejszego zapytania)?

Odpowiedź:

Zamawiający wyraża zgodę na oryginalne certyfikaty w języku angielskim

Pytanie 4

Dotyczy Pakietu nr 7:

W związku z tym, że umowa zakłada możliwość składania zamówień cząstkowych proszę o określenie maksymalnej liczby zamówień dla pakietu nr 7.

Odpowiedź:

Zamawiającym informuje, iż realizacja odbywać się będzie zgodnie z ogólnymi warunkami postepowania.

DYREKTOR
dr inż. Adam Sidor

Certificate of Analysis

PATULIN IN ACETONITRILE

1. General information

This document is designed and the certified value(s) and uncertainty(ies) are determined in accordance with ISO Guide 31 [1] and Eurachem / CITAC Guides [2,3].

2. Description of the Reference Material (RM)

Name:	Patulin in acetonitrile
CAS number:	149-29-1
Catalog number:	10000347 (5mL), 10003659 (1mL)
Lot #:	1000020228
Certificate version:	1
Expiry date:	28.02.2025
Starting material:	Patulin, Lot # S21271P, Romer Labs Diagnostic GmbH
Matrix:	Acetonitrile, LiChrosolv Lot # I1116230043, Merck, 1000302500
Physical description of RM:	Solution of Patulin in acetonitrile
Packaging and amount of RM:	10000347: Amber glass ampoules fitted with teflon faced butyl septa and PP screw caps, solution of 5 mL 10003659: Amber glass ampoules fitted with teflon faced butyl septa and aluminium crimp cap, solution of 1 mL
Name and address of the supplier:	Romer Labs Division Holding GmbH Technopark 5 3430 Tulln, Austria www.romerlabs.com, office-europe@romerlabs.com

2.1 Intended use of the RM

- for laboratory use only
- calibration of analytical instruments

2.2 Instruction for the correct use of the RM

The ampoules should be stored at -18 to -22°C or below in a dark place. Before usage of the RM, the ampoules should be allowed to warm to room temperature. The recommended minimum sub-sample amount for all kinds of application is 100 µL. The expiry date of this RM is based on the current knowledge and holds only for proper storage conditions in the originally closed flasks/packages.

2.3 Hazardous situation

The normal laboratory safety precautions should be observed when working with this RM. Further details for the handling of this RM are available as material safety data sheet (MSDS).

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3. Certified values and their uncertainties

Patulin in acetonitrile		
Compound	**Mass concentration [a]**	
	Certified value [b]	Uncertainty [c]
Patulin	100.0 µg/mL	± 1.4 µg/mL

[a] *Values are based on preparation data and confirmed experimentally by HPLC-UV*
[b] *Mass concentration based on weighed amount, purity and dilution step*
[c] *Expanded uncertainty U (k = 2) of the value u_c according to GUM [4]*

3.1 Calculation of uncertainty

The uncertainty of the calibrant solution was calculated on the basis of preparation [5].

Uncertainty components	Description	Standard uncertainty (u)	
Purity (P) of solid Patulin (the uncertainty of the purity corresponds to the standard deviation of repeated measurements)	P = 99.3 ± 1.0 %	**u (P) = 0.6 %**	a
Weighing procedure weighted sample: m_{ws}= 50.348 mg	U(m) = 0.0012 mg + 8.81 * 10^{-6} * m_{Toxin} u(m) = U(m)/2	**u (m) = 0.008 mg**	b
Dilution procedure volumetric flask: V_f = 500 mL	calibration: 500 mL ± 0.25 mL repeatability: 0.1 mL volume expansion solvent	u (cal) = 0.1 mL u (rep) = 0.1 mL u (Vol. exp.) = 1.2 mL **u (V) = 1.2 mL**	c d e f

[a] *Maximum tolerance of purity (rectangular distribution) was divided by $\sqrt{3}$*
[b] *Calculation of this u-value is based upon the uncertainty formula for the weighed amount as given in the calibration report from annual balance calibration*
[c] *A triangular distribution (division by $\sqrt{6}$) was chosen for the calculation of u (cal)*
[d] *Based on a series of ten fill and weigh experiments on a typical 500 mL flask; the value was used directly as a standard deviation*
[e] *Based on the density of 0.7857 g/cm³ at temperature T = 20°C and a maximum temperature variation of ± 3°C, of volume expansion, relative volume expansion coefficient of acetonitrile is 1370 * 10^{-6}/°C [6], volume expansion term (rectangular distribution) was divided by $\sqrt{3}$*
[f] *The three contributions are combined to give the u (V) = $\sqrt{u(cal)^2 + u(rep)^2 + u(Vol.\,\mathrm{exp.})^2}$*

Calculation of the combined uncertainty u_c and the expanded standard uncertainty U

$$c_{Toxin} = \frac{10 \times m_{ws} \times P}{V_f} = \frac{10 \times 50.348 \times 99.3}{500} = 100.0\ mg/L$$

$$\frac{u_c(c_{Toxin})}{c_{Toxin}} = \sqrt{\left[\frac{u(P)}{P}\right]^2 + \left[\frac{u(m)}{m_{ws}}\right]^2 + \left[\frac{u(V)}{V_f}\right]^2} = \sqrt{\left[\frac{0.6}{99.3}\right]^2 + \left[\frac{0.0008}{50.348}\right]^2 + \left[\frac{1.2}{500}\right]^2} = 0.007$$

$$u_c(c_{Toxin}) = c_{Toxin} \times 0.007 = 100.0 \times 0.007 = 0.7\ mg/L$$

Calculation of expanded standard uncertainty U using a coverage factor k = 2

$$U(c_{Toxin}) = u_c(c_{Toxin}) \times 2 = 0.7 \times 2 = 1.4\ mg/L \approx 1.4\ \mu g/mL$$

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4. Discussion of traceability

This calibrant is certified on the basis of gravimetric preparation [5]. Thus the certified value (mass concentration of Patulin) is based on the weighed amount of the starting material and is therefore traceable to the stated purity of the solid raw material. High purity material represents a practical realization of concentration units, through conversion of mass to molar quantity.

5. Confirmation of certified value by HPLC-UV

The certified concentration of Patulin of the gravimetric prepared solution was confirmed by HPLC-UV against an independently prepared reference batch of Patulin calibrant.

column	Phenomenex Kinetex C18, 100x 3mm, 2.6µmm	
injection volume	25 µL sample	
solvent A	acetonitrile / water (5 / 95)	
solvent B	acetonitrile	
sample dilution	1:10 with water	
flow rate	0.5 mL / min	
gradient	time in minutes (min)	% solvent B
	0.0 – 3.0	0
	3.0 – 6.0	0 - 33
	6.0 – 10.0	33 - 65
	10.0 – 12.0	65
	12.0 – 12.1	65 - 0
	12.1 – 16.0	0
DAD settings	276 nm	

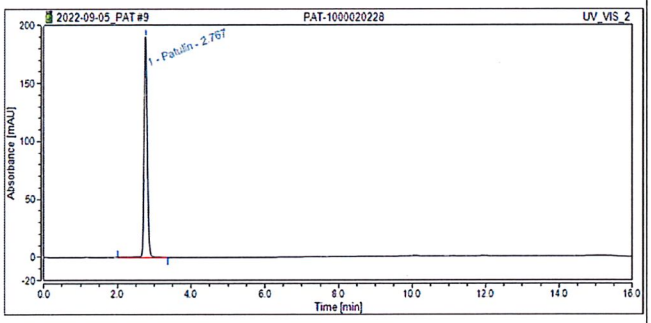

Figure 1: HPLC-UV chromatogram of Patulin

	time [min]	area	concentration [a] [µg/mL]
Patulin	2.767	18.823	98.6 ± 3.0

[a] Mean of 6 replicate measurements against reference batch, confidence interval with P = 95 %

6. Further information

The purchaser must determine the suitability of this product for its particular use. Romer Labs Division Holding GmbH makes no warranty of any kind, express or implied, other than its products meet all quality control standards set by Romer Labs Division Holding GmbH. We do not guarantee that the product can be used for a special application.

approved for release by: Michaela Streicher date: 13.09.2022

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References:

[1] ISO Guide 31:2015 - 1-18, *"Reference materials – contents of certificates, labels and accompanying documentation"*

[2] Eurachem / CITAC Guide, 1-37, (2003), *"Traceability in Chemical Measurement"*

[3] Eurachem / CITAC Guide CG4, 1-133, (QUAM:2012.P1), *"Quantifying Uncertainty in Analytical Measurement", 3rd Ed.*

[4] International Organization for Standardization (ISO), (2008), *"Guide to the expression of uncertainty in measurement"*, (GUM 1995 with minor corrections) 1st Ed. Geneva, Switzerland

[5] R.D. Josephs, R. Krska, S. MacDonald, P. Wilson, H. Pettersson, J. AOAC Int. **86**, 50-60, (2003), *"Preparation of a Calibrant as Certified Reference Material for Determination of the Fusarium Mycotoxin Zearalenone"*

[6] E.W. Flick, (1998), *"Industrial Solvents Handbook"*, 5th Ed., Noyes Data Corp. Westwood NJ

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Certificate of Analysis

AFLATOXIN M1 IN ACETONITRILE

1. General information

This document is designed and the certified value(s) and uncertainty(ies) are determined in accordance with ISO Guide 31 [1] and Eurachem / CITAC Guides [2,3].

2. Description of the Reference Material (RM)

Name:	Aflatoxin M1 in acetonitrile
CAS number:	6795-23-9
Catalog number:	10000349 (5 mL), 10003661 (1 mL)
Lot #:	1000019171
Certificate version:	1
Expiry date:	24.01.2025
Starting material:	Aflatoxin M1, Lot #S16142M, Romer Labs Diagnostic GmbH
Matrix:	Acetonitrile, LiChrosolv Lot # I1116230043, Merck 1000302500
Physical description of RM:	Solution of Aflatoxin M1 in acetonitrile
Packaging and amount of RM:	10000349: Amber glass ampoules fitted with teflon faced butyl septa and PP screw caps, solution of 5 mL 10003661: Amber glass ampoules fitted with teflon faced butyl septa and aluminium crimp cap, solution of 1 mL
Name and address of the supplier:	Romer Labs Division Holding GmbH Technopark 5 3430 Tulln, Austria www.romerlabs.com, office-europe@romerlabs.com

2.1 Intended use of the RM

- for laboratory use only
- calibration of analytical instruments

2.2 Instruction for the correct use of the RM

The ampoules should be stored at -18 to -22°C or below in a dark place. Before usage of the RM, the ampoules should be allowed to warm to room temperature. The recommended minimum sub-sample amount for all kinds of application is 100 µL. The expiry date of this RM is based on the current knowledge and holds only for proper storage conditions in the originally closed flasks/packages.

2.3 Hazardous situation

The normal laboratory safety precautions should be observed when working with this RM. Further details for the handling of this RM are available as material safety data sheet (MSDS).

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3. Certified values and their uncertainties

Aflatoxin M1 in acetonitrile		
Compound	**Mass concentration [a]**	
	Certified value [b]	Uncertainty [c]
Aflatoxin M1	0.502 µg/mL	± 0.01 µg/mL

[a] Values are based on preparation data and confirmed experimentally by HPLC-UV
[b] Mass concentration based on weighed amount, purity and dilution steps
[c] Expanded uncertainty U (k = 2) of the value u_c according to GUM [4]

3.1 Calculation of uncertainty

The uncertainty of the calibrant solution was calculated on the basis of preparation [5].

Uncertainty components	Description	Standard uncertainty (u)	
Purity (P) of solid Aflatoxin M1 (the uncertainty of the purity corresponds to the standard deviation of repeated measurements)	P = 99 ± 1 %	**u (P) = 0.6 %**	a
Weighing procedure weighted sample: m_{ws}= 1.268 mg	U(m) = 0.0012 mg + 8.81 * 10^{-6} * m_{Toxin} u(m) = U(m)/2	**u (m) = 0.0006 mg**	b
Dilution procedure volumetric flask 1: V_{f1} = 250 mL volumetric flask 2: V_{f2} = 250 mL one-mark glass pipette: V_p = 25 mL	calibration flask 1: 250 mL ± 0.15 mL repeatability flask 1: 0.02 mL volume expansion solvent flask 1 calibration flask 2: 250 mL ± 0.15 mL repeatability flask 2: 0.02 mL volume expansion solvent flask 2 calibration pipette: 25 mL ± 0.03 mL volume expansion solvent pipette	u (cal1) = 0.06 mL u (rep1) = 0.02 mL u (Vol. exp.1) = 0.59 mL **u (V1) = 0.6 mL** u (cal2) = 0.06 mL u (rep2) = 0.02 mL u (Vol. exp.2) = 0.59 mL **u (V2) = 0.6 mL** u (cal3) = 0.01 mL u (Vol. exp.3) = 0.06 mL **u (V3) = 0.06 mL**	c d e f g h i j k l m

[a] Maximum tolerance of purity was divided by $\sqrt{3}$

[b] Calculation of this u-value is based upon the uncertainty formula for the weighed amount as given in the calibration report from annual balance calibration

[c,g,k] A triangular distribution (division by $\sqrt{6}$) was chosen for the calculation of u (cal)

[d,h] Based on a series of ten fill and weigh experiments on a typical 250 mL flask; the values were used directly as a standard deviation

*[e,i,l] Based on the density of 0.7857 g/cm³ at temperature T = 20°C and a maximum temperature variation of ± 3°C, of volume expansion relative volume expansion coefficient of acetonitrile is 1370 * 10^{-6}/°C [6], volume expansion term (rectangular distribution) was divided by $\sqrt{3}$*

[f,j,m] All contributions are combined to give the u (V) = $\sqrt{u(cal)^2 + u(rep)^2 + u(Vol.\,\mathrm{exp.})^2}$

Calculation of the combined uncertainty u_c and the expanded standard uncertainty U

$$c_{Toxin} = \frac{10 \times m_{ws} \times P \times V_p}{V_{f1} \times V_{f2}} = \frac{10 \times 1.268 \times 99 \times 25}{250 \times 250} = 0.502\ mg/L$$

$$\frac{u_c(c_{Toxin})}{c_{Toxin}} = \sqrt{\left[\frac{u(P)}{P}\right]^2 + \left[\frac{u(m)}{m_{ws}}\right]^2 + \left[\frac{u(V1)}{V_{f1}}\right]^2 + \left[\frac{u(V2)}{V_{f2}}\right]^2 + \left[\frac{u(V3)}{V_p}\right]^2} = \sqrt{\left[\frac{0.6}{99}\right]^2 + \left[\frac{0.0006}{1.268}\right]^2 + \left[\frac{0.6}{250}\right]^2 + \left[\frac{0.6}{250}\right]^2 + \left[\frac{0.06}{25}\right]^2} = 0.009$$

$$u_c(c_{Toxin}) = c_{Toxin} \times 0.009 = 0.502 \times 0.009 = 0.005\ mg/L$$

Calculation of expanded standard uncertainty U using a coverage factor k = 2

$$U(c_{Toxin}) = u_c(c_{Toxin}) \times 2 = 0.005 \times 2 = 0.01\ mg/L = 0.01\ \mu g/mL$$

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4. Discussion of traceability

This calibrant is certified on the basis of gravimetric preparation [5]. Thus the certified value (mass concentration of Aflatoxin M1) is based on the weighed amount of the starting material and is therefore traceable to the stated purity of the solid raw material. High purity material represents a practical realization of concentration units, through conversion of mass to molar quantity.

5. Confirmation of certified value by HPLC-UV

The certified concentration of Aflatoxin M1 of the gravimetric prepared solution was confirmed by HPLC-UV against an independently prepared reference batch of Aflatoxin M1.

column	Phenomenex Kinetex C18, 100x 3mm, 2.6µmm
injection volume	25 µL sample
solvent A	water / acetonitrile / methanol 57/17/26
oven	35°C
flow rate	0.5 mL / min
DAD settings	365 nm
sample dilution	1:5 with solvent A

	time	area	height	concentration [a]
Aflatoxin M1	3.300	0.446	2.748	0.513 ± 0.02 µg/mL

[a] Mean of 6 replicate measurements against reference batch, confidence interval with P = 95 %

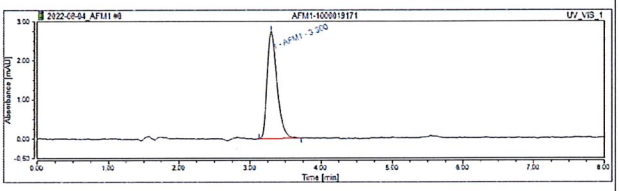

Figure 1: HPLC-UV chromatogram of Aflatoxin M1 calibrant

6. Further information

The purchaser must determine the suitability of this product for its particular use. Romer Labs Division Holding GmbH makes no warranty of any kind, express or implied, other than its products meet all quality control standards set by Romer Labs Division Holding GmbH. We do not guarantee that the product can be used for a special application.

approved for release by: Lisa Oberndorfer date: 10.08.2022

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References:

[1] ISO Guide 31:2015 - 1-18, "Reference materials – contents of certificates, labels and accompanying documentation"

[2] Eurachem / CITAC Guide, 1-37, (2003), *"Traceability in Chemical Measurement"*

[3] Eurachem / CITAC Guide CG-4, 1-133, (QUAM:2012.P1), *"Quantifying Uncertainty in Analytical Measurement", 3rd Ed.*

[4] International Organization for Standardization (ISO), (2008), *"Guide to the expression of uncertainty in measurement"*, (GUM 1995 with minor corrections) 1st Ed. Geneva, Switzerland

[5] R.D. Josephs, R. Krska, S. MacDonald, P. Wilson, H. Pettersson, J. AOAC Int. **86**, 50-60, (2003), *"Preparation of a Calibrant as Certified Reference Material for Determination of the Fusarium Mycotoxin Zearalenone"*

[6] E.W. Flick, (1998), *"Industrial Solvents Handbook"*, 5th Ed., Noyes Data Corp. Westwood NJ

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CERTIFIED REFERENCE MATERIAL CERTIFICATE ISO 17034

Certified Reference Material

This certificate is designed in accordance with ISO 17034 and ISO Guide 31. This reference material (RM) was designed, produced and verified in accordance with ISO/IEC 17025, ISO 17034 and a registered quality management system ISO 9001.

Product Name

Aflatoxin B1 2 µg/mL in Acetonitrile, Solution of Aflatoxin B1 in Acetonitrile

Product Code
10006702

CAS No.
1162-65-8

Mol. Weight
312.27

Mol. Formula
C17H12O6

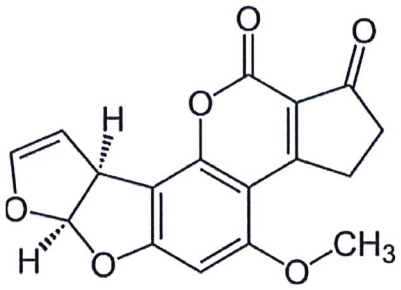
Volume (ml)
1

Lot Number
1000007891

Format
Solution

Expiry Date
7 Mar 2024

Storage Temp
-18 to -22°C



CERTIFIED	CERTIFIED
Concentration 2.00 µg/mL	Expanded Uncertainty (U) 0.07 µg/mL

Uncertainty
The certified value(s) and uncertainty(ies) are determined in accordance with EURACHEM/CITAC Guide for "Quantifying Uncertainty in Analytical Measurement, 3rd edition", with an 95% confidence level (k=2). Uncertainty is based on the Total Combined Uncertainty, including uncertainties of characterisation and stability testing. Stability values are based on real evidence opposed to simulation.

The producer certifies that this reference material meets the specification stated in this certificate until the expiry date, provided it is stored unopened at the recommended temperature herein. Product warranties for this reference material are set out in the terms and conditions of purchase.

CERTIFIED BY	CERTIFIED ON		
Ing. M. Streicher	31 Mar 2022	Michaela Streicher	RM Release

Romer Labs Division Holding GmbH
Erber Campus 1, 3131 Getzersdorf, Austria.

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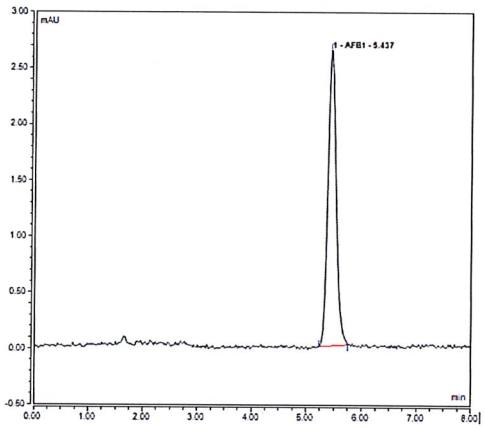
CERTIFIED REFERENCE MATERIAL CERTIFICATE ISO 17034

CHROMATOGRAM



Instrument
Thermo Fisher UPLC 3000

Detection
DAD

Column
Phenomenex Kinetex, 100 x 3 mm, 2,6µ

Method Details
see Batch Information

Inj.-Vol.
25 µl

Flow
0,3 ml/min

Method of Preparation
The certified value is based on gravimetric and volumetric preparation of this RM. This RM has been confirmed by the appropriate analytical techniques.

Method of Characterisation
Purity was determined by quantitative NMR.

Method of Identification
HPLC-UV, MS, NMR

Batch Information
Solvent: Acetonitrile, Acetonitrile, Merck 1000302500, Lot I1098930024, 1000 mL.

Aflatoxin B2 <0.1%, Aflatoxin G1 <0.1%, Aflatoxin G2 <0.1%, Sum Aflatoxins <0.3%

Method Details:
Eluent: water / acetonitrile / methanol 57/17/26
Isocratic 10 min
Oven 35 °C
Sample dilution 1:10 with eluent
DAD setting 356 nm

Compound Name	Lot No.	Chemical Purity
Aflatoxin B1	AF027	95%

Producer
Romer Labs Division Holding GmbH
Technopark 5
3430 Tulln, Austria

Intended Use
This reference material (RM) is intended for use in a laboratory as a calibration and quality control standard or in method development for analytical techniques.

Safety
Proper precautions should be observed while handling. See Safety Data Sheet.

Traceability
The balances used for gravimetric measurements are calibrated with weights traceable to the national standards. The calibration of the balances is verified daily internally and at least annually by an external accredited calibration service. Chromatographic methods are traceable to the International System of Units (SI).

Storage
The RM should be stored in the original sealed container at the indicated temperature.

Instructions for use
The RM should be used shortly after opening to avoid concentration changes due to evaporation. It is recommended to use 100 µL as the minimum sample size and if less material is used, to increase the certified uncertainty by a factor of two for half sample and four for a quarter of sample. If storage after opening is necessary, the RM should be tightly closed and kept from light and moisture.

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Erber Campus 1, 3131 Getzersdorf, Austria.

Akkreditierung Austria A 0457 ISO/IEC 17034

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CERTIFIED REFERENCE MATERIAL CERTIFICATE ISO 17034

Certified Reference Material

This certificate is designed in accordance with ISO 17034 and ISO Guide 31. This reference material (RM) was designed, produced and verified in accordance with ISO/IEC 17025, ISO 17034 and a registered quality management system ISO 9001.

Product Name

Aflatoxin B2 0,5 µg/mL in Acetonitrile, Solution of Aflatoxin B2 in Acetonitrile

Product Code
10006704

CAS No.
7220-81-7

Mol. Weight
314.29

Mol. Formula
C17H14O6

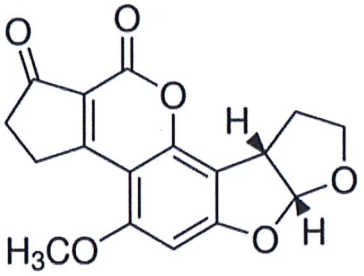
Volume (ml)
1

Lot Number
1000007892

Format
Solution

Expiry Date
7 Mar 2024

Storage Temp
-18 to -22°C



CERTIFIED	CERTIFIED
Concentration 0.51 µg/mL	Expanded Uncertainty (U) 0.03 µg/mL

Uncertainty
The certified value(s) and uncertainty(ies) are determined in accordance with EURACHEM/CITAC Guide for "Quantifying Uncertainty in Analytical Measurement, 3rd edition", with an 95% confidence level (k=2). Uncertainty is based on the Total Combined Uncertainty, including uncertainties of characterisation and stability testing. Stability values are based on real evidence opposed to simulation.

The producer certifies that this reference material meets the specification stated in this certificate until the expiry date, provided it is stored unopened at the recommended temperature herein. Product warranties for this reference material are set out in the terms and conditions of purchase.

CERTIFIED BY	CERTIFIED ON		
Ing. M. Streicher	31 Mar 2022	Michaela Streicher	RM Release

Romer Labs Division Holding GmbH
Erber Campus 1, 3131 Getzersdorf, Austria.

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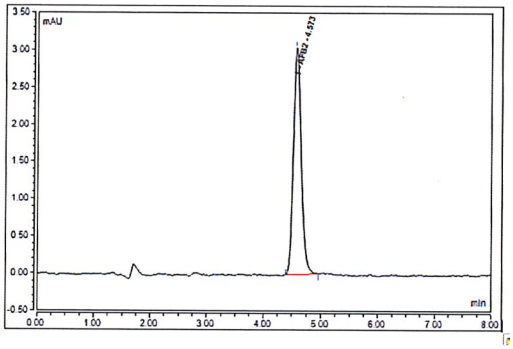
CERTIFIED REFERENCE MATERIAL CERTIFICATE ISO 17034

CHROMATOGRAM



Instrument
Thermo Fisher UPLC 3000

Detection
DAD

Column
Phenomenex Kinetex, 100 x 3 mm, 2,6µ

Method Details
see Batch Information

Inj.-Vol.
25 µl

Flow
0,3 ml/min

Method of Preparation
The certified value is based on gravimetric and volumetric preparation of this RM. This RM has been confirmed by the appropriate analytical techniques.

Method of Characterisation
Purity was determined by quantitative NMR.

Method of Identification
HPLC-UV, MS, NMR

Batch Information
Solvent: Acetonitrile, Acetonitrile, Merck 1000302500, Lot I1098930024, 2000 mL.

Aflatoxin B1 <0.1%, Aflatoxin G1 <0.1%, Aflatoxin B2 <0.1%, Sum Aflatoxins <0.3%

Method Details:
Eluent: water / acetonitrile / methanol 57/17/26
Isocratic 10 min
Oven 35 °C
Sample dilution 1:10 with eluent
DAD setting 356 nm

Compound Name	Lot No.	Chemical Purity
Aflatoxin B2	AFb009	94%

Producer
Romer Labs Division Holding GmbH
Technopark 5
3430 Tulln, Austria

Intended Use
This reference material (RM) is intended for use in a laboratory as a calibration and quality control standard or in method development for analytical techniques.

Safety
Proper precautions should be observed while handling. See Safety Data Sheet.

Traceability
The balances used for gravimetric measurements are calibrated with weights traceable to the national standards. The calibration of the balances is verified daily internally and at least annually by an external accredited calibration service. Chromatographic methods are traceable to the International System of Units (SI).

Storage
The RM should be stored in the original sealed container at the indicated temperature.

Instructions for use
The RM should be used shortly after opening to avoid concentration changes due to evaporation. It is recommended to use 100 µL as the minimum sample size and if less material is used, to increase the certified uncertainty by a factor of two for half sample and four for a quarter of sample. If storage after opening is necessary, the RM should be tightly closed and kept from light and moisture.

ISO 9001 CERTIFIED ISO 14001 CERTIFIED CO_2 NEUTRAL

Romer Labs Division Holding GmbH
Erber Campus 1, 3131 Getzersdorf, Austria.

Akkreditierung Austria A 0457 ISO/IEC 17034

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CERTIFIED REFERENCE MATERIAL CERTIFICATE ISO 17034

Certified Reference Material

This certificate is designed in accordance with ISO 17034 and ISO Guide 31. This reference material (RM) was designed, produced and verified in accordance with ISO/IEC 17025, ISO 17034 and a registered quality management system ISO 9001.

Product Name

Aflatoxin G1 2 µg/mL in Acetonitrile, Solution of Aflatoxin G1 in Acetonitrile

Product Code
10006706

CAS No.
1165-39-5

Mol. Weight
328.27

Mol. Formula
C17H12O7

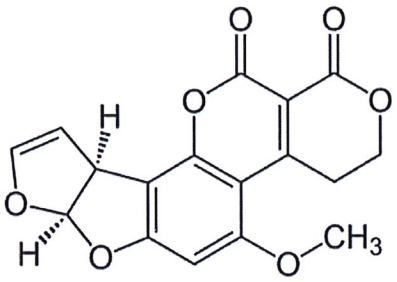
Volume (ml)
1

Lot Number
1000008082

Format
Solution

Expiry Date
27 Mar 2024

Storage Temp
-18 to -22°C



CERTIFIED	CERTIFIED
Concentration 2.02 µg/mL	Expanded Uncertainty (U) 0.08 µg/mL

Uncertainty
The certified value(s) and uncertainty(ies) are determined in accordance with EURACHEM/CITAC Guide for "Quantifying Uncertainty in Analytical Measurement, 3rd edition", with an 95% confidence level (k=2). Uncertainty is based on the Total Combined Uncertainty, including uncertainties of characterisation and stability testing. Stability values are based on real evidence opposed to simulation.

The producer certifies that this reference material meets the specification stated in this certificate until the expiry date, provided it is stored unopened at the recommended temperature herein. Product warranties for this reference material are set out in the terms and conditions of purchase.

CERTIFIED BY	CERTIFIED ON		
Ing. M. Streicher	31 Mar 2022	Michaela Streicher	RM Release

Romer Labs Division Holding GmbH
Erber Campus 1, 3131 Getzersdorf, Austria.

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Akkreditierung Austria 0457 ISO/IEC 17034

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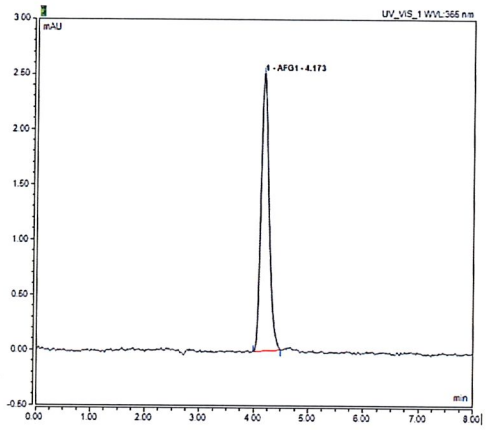
CERTIFIED REFERENCE MATERIAL CERTIFICATE ISO 17034

CHROMATOGRAM



Instrument
Thermo Fisher UPLC 3000

Detection
DAD

Column
Phenomenex Kinetex, 100 x 3 mm, 2,6µ

Method Details
see Batch Information

Inj.-Vol.
25 µl

Flow
0,3 ml/min

Method of Preparation
The certified value is based on gravimetric and volumetric preparation of this RM. This RM has been confirmed by the appropriate analytical techniques.

Method of Characterisation
Purity was determined by quantitative NMR.

Method of Identification
HPLC-UV, MS, NMR

Batch Information
Solvent: Acetonitrile, Acetonitrile, Merck 1000302500, Lot I1098930024, 1000 mL.

Aflatoxin B1 0.26%, Aflatoxin B2 <0.1%, Aflatoxin G2 0.26%, Sum Aflatoxins <0.62%

Method Details:
Eluent: water / acetonitrile / methanol 57/17/26
Isocratic 10 min
Oven 35 °C
Sample dilution 1:10 with eluent
DAD setting 356 nm

Compound Name	Lot No.	Chemical Purity
Aflatoxin G1	AFg018Aa	96%

Producer
Romer Labs Division Holding GmbH
Technopark 5
3430 Tulln, Austria

Intended Use
This reference material (RM) is intended for use in a laboratory as a calibration and quality control standard or in method development for analytical techniques.

Safety
Proper precautions should be observed while handling. See Safety Data Sheet.

Traceability
The balances used for gravimetric measurements are calibrated with weights traceable to the national standards. The calibration of the balances is verified daily internally and at least annually by an external accredited calibration service. Chromatographic methods are traceable to the International System of Units (SI).

Storage
The RM should be stored in the original sealed container at the indicated temperature.

Instructions for use
The RM should be used shortly after opening to avoid concentration changes due to evaporation. It is recommended to use 100 µL as the minimum sample size and if less material is used, to increase the certified uncertainty by a factor of two for half sample and four for a quarter of sample. If storage after opening is necessary, the RM should be tightly closed and kept from light and moisture.

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Romer Labs Division Holding GmbH
Erber Campus 1, 3131 Getzersdorf, Austria.

Akkreditierung Austria A 0457 ISO/IEC 17034

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CERTIFIED REFERENCE MATERIAL CERTIFICATE ISO 17034

Certified Reference Material

This certificate is designed in accordance with ISO 17034 and ISO Guide 31. This reference material (RM) was designed, produced and verified in accordance with ISO/IEC 17025, ISO 17034 and a registered quality management system ISO 9001.

Product Name

Aflatoxin G2 0,5 µg/mL in Acetonitrile, Solution of Aflatoxin G2 in Acetonitrile

Product Code
10006708

CAS No.
7241-98-7

Mol. Weight
330.29

Mol. Formula
C17H14O7

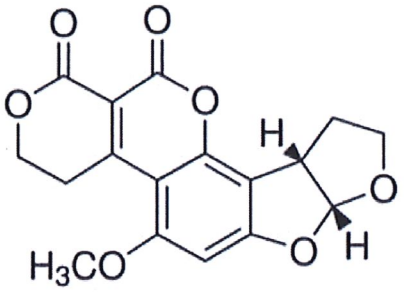
Volume (ml)
1

Lot Number
1000007894

Format
Solution

Expiry Date
27 Mar 2024

Storage Temp
-18 to -22°C



CERTIFIED	CERTIFIED
Concentration 0.51 µg/mL	Expanded Uncertainty (U) 0.03 µg/mL

Uncertainty
The certified value(s) and uncertainty(ies) are determined in accordance with EURACHEM/CITAC Guide for "Quantifying Uncertainty in Analytical Measurement, 3rd edition", with an 95% confidence level (k=2). Uncertainty is based on the Total Combined Uncertainty, including uncertainties of characterisation and stability testing. Stability values are based on real evidence opposed to simulation.

The producer certifies that this reference material meets the specification stated in this certificate until the expiry date, provided it is stored unopened at the recommended temperature herein. Product warranties for this reference material are set out in the terms and conditions of purchase.

CERTIFIED BY	CERTIFIED ON		
Ing. M. Streicher	30 May 2022	Michaela Streicher	RM Release

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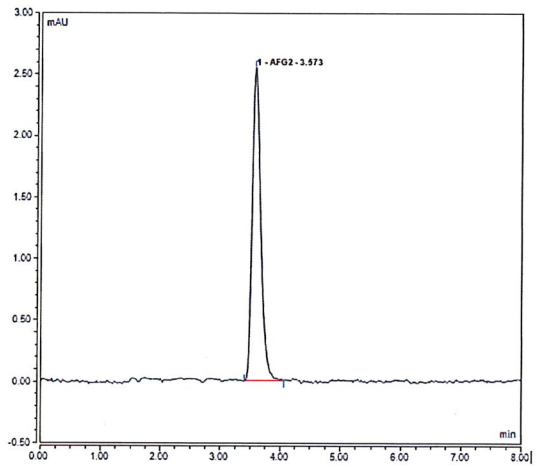
CERTIFIED REFERENCE MATERIAL CERTIFICATE ISO 17034

CHROMATOGRAM



Instrument
Thermo Fisher UPLC 3000

Detection
DAD

Column
Phenomenex Kinetex, 100 x 3 mm, 2,6µ

Method Details
see Batch Information

Inj.-Vol.
25 µl

Flow
0,3 ml/min

Method of Preparation
The certified value is based on gravimetric and volumetric preparation of this RM. This RM has been confirmed by the appropriate analytical techniques.

Method of Characterisation
Purity was determined by quantitative NMR.

Method of Identification
HPLC-UV, MS, NMR

Batch Information
Solvent: Acetonitrile, Acetonitrile, Merck 1000302500, Lot I1098930024, 2000 mL.

Aflatoxin B2 <0.1%, Aflatoxin G1 <0.1%, Aflatoxin G2 <0.1%, Sum Aflatoxins <0.3%

Method Details:
Eluent: water / acetonitrile / methanol 57/17/26
Isocratic 10 min
Oven 35 °C
Sample dilution 1:10 with eluent
DAD setting 356 nm

Compound Name	Lot No.	Chemical Purity
Aflatoxin G2	AFg020A	98%

Producer
Romer Labs Division Holding GmbH
Technopark 5
3430 Tulln, Austria

Intended Use
This reference material (RM) is intended for use in a laboratory as a calibration and quality control standard or in method development for analytical techniques.

Safety
Proper precautions should be observed while handling. See Safety Data Sheet.

Traceability
The balances used for gravimetric measurements are calibrated with weights traceable to the national standards. The calibration of the balances is verified daily internally and at least annually by an external accredited calibration service. Chromatographic methods are traceable to the International System of Units (SI).

Storage
The RM should be stored in the original sealed container at the indicated temperature.

Instructions for use
The RM should be used shortly after opening to avoid concentration changes due to evaporation. It is recommended to use 100 µL as the minimum sample size and if less material is used, to increase the certified uncertainty by a factor of two for half sample and four for a quarter of sample. If storage after opening is necessary, the RM should be tightly closed and kept from light and moisture.

ISO 9001 CERTIFIED ISO 14001 CERTIFIED CO_2 NEUTRAL

Romer Labs Division Holding GmbH
Erber Campus 1, 3131 Getzersdorf, Austria.

Akkreditierung Austria A 0457 ISO/IEC 17034

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CERTIFIED REFERENCE MATERIAL CERTIFICATE ISO 17034

Certified Reference Material

This certificate is designed in accordance with ISO 17034 and ISO Guide 31. This reference material (RM) was designed, produced and verified in accordance with ISO/IEC 17025, ISO 17034 and a registered quality management system ISO 9001.

Product Name
Deoxynivalenol 100 µg/mL in Acetonitrile, Solution of Deoxynivalenol in Acetonitrile

Product Code
10006716

Lot Number
1000007890

CAS No.
51481-10-8

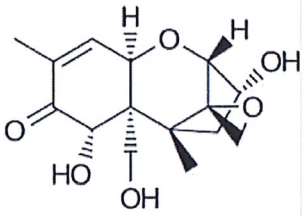
Format
Solution

Mol. Weight
296.32

Expiry Date
6 Mar 2024

Mol. Formula
C15H20O6

Storage Temp
2-8°C



Volume (ml)
1

CERTIFIED	CERTIFIED
Concentration 99.98 µg/mL	Expanded Uncertainty (U) 2.98 µg/mL

Uncertainty
The certified value(s) and uncertainty(ies) are determined in accordance with EURACHEM/CITAC Guide for "Quantifying Uncertainty in Analytical Measurement, 3rd edition", with an 95% confidence level (k=2). Uncertainty is based on the Total Combined Uncertainty, including uncertainties of characterisation and stability testing. Stability values are based on real evidence opposed to simulation.

The producer certifies that this reference material meets the specification stated in this certificate until the expiry date, provided it is stored unopened at the recommended temperature herein. Product warranties for this reference material are set out in the terms and conditions of purchase.

CERTIFIED BY	CERTIFIED ON		
Ing. M. Streicher	29 Mar 2022	Michaela Streicher	RM Release

Romer Labs Division Holding GmbH
Erber Campus 1, 3131 Getzersdorf, Austria.

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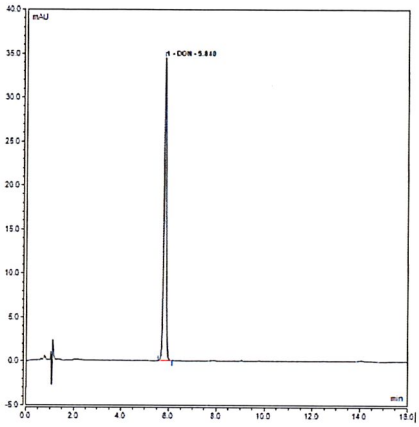
CERTIFIED REFERENCE MATERIAL CERTIFICATE ISO 17034

CHROMATOGRAM



Instrument
Thermo Fisher UPLC 3000

Detection
DAD

Column
Phenomenex Kinetex, 100 x 3 mm, 2,6µ

Method Details
see Batch Information

Inj.-Vol.
10 µl

Flow
0,5 ml/min

Method of Preparation
The certified value is based on gravimetric and volumetric preparation of this RM. This RM has been confirmed by the appropriate analytical techniques.

Method of Characterisation
Purity was determined by quantitative NMR.

Method of Identification
HPLC-UV, MS, NMR

Batch Information
Solvent: Acetonitrile, Acetonitrile, Merck 1000302500, Lot I1098930024, 1000 mL.

Method Details:
Eluent A: water + 5% acetonitrile
Eluent B: acetonitrile
Eluent A->B: 16 min
Oven 35 °C
Sample dilution 1:10 with water
DAD setting 191, 217, 250, 276 nm

Compound Name	Lot No.	Chemical Purity
Deoxynivalenol	S14341D	99%

Producer
Romer Labs Division Holding GmbH
Technopark 5
3430 Tulln, Austria

Intended Use
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