5.1.2e)

Van: 5.1.2e)
Verzonden: woensdag 17 februari 2021 14:10
Aan: 5.1.2e minvws.nl; 5.1.5
CC: 5.1.2e 5.1.2e)
Onderwerp: FW: Syringe - Covid19 vaccination campaign (7 doses)
Bijlagen: VPEX syringe presentation.pdf

Digibalie svp innemen op PDC-19

Met vriendelijke groet,

5.1.2e
5.1.2e

Ministerie van Volksgezondheid, Welzijn en Sport | Directie Bestuurlijk en Politieke Zaken |
Parnassusplein 5 | 2511 VX | Den Haag | Postbus 20350 | 2500 EJ | Den Haag |
5.1.2e 5.1.2e 5.1.2e .nl | www.rijksoverheid.nl |
5.1.2e

Van: 5.1.2e <5.1.2e @vpex.fr>
Verzonden: woensdag 17 februari 2021 13:53
Aan: Minister voor Medische Zorg en Sport <5.1.2e minvws.nl>
Onderwerp: Syringe - Covid19 vaccination campaign (7 doses)

Dear Mrs Van Ark,

I am contacting you on behalf of Vpex company, a French company specialized with hygiene, sanitary and health products.

We are currently working with important groups and organizations such as *Santé Publique France*, the French Public Health Agency as part of the Covid19 vaccination campaign

As part of the Covid19 vaccination campaign, we offer a special syringe, with a "low-dead" volume. The needle, conceived to have a minimum quantity of liquid left, enables to save between 20 and 30% of the vaccine for each shot. The benefits of this type of syringe are numerous. The "low-dead" volume enables to save a significant amount of vaccine and the number of shots is optimized: when using this syringe, 7 shots can be administrated with one dose (instead of 5 shots with other regular syringes). The benefits are numerous: less waste of product, economical saving, time saving during vaccination and less packaging.

It is a 1ML, 25G syringe, highly recommended for the Covid19 vaccine. This syringe is under a patent protection and we hold international exclusive rights for this type of product.

We have already sold this syringe to France, Belgium and Sweden and we are in advanced discussions with other European countries such as Portugal and Montenegro.
We were also referenced on the CE Clearing House platform.

I have attached a full presentation and the test report of an independent laboratory that confirms the extraction of 7 doses.

I remain at your entire disposal for any further information you would need.

Best regards,

5.1.2e
www.vpex.fr

VPEX
SOLUTIONS

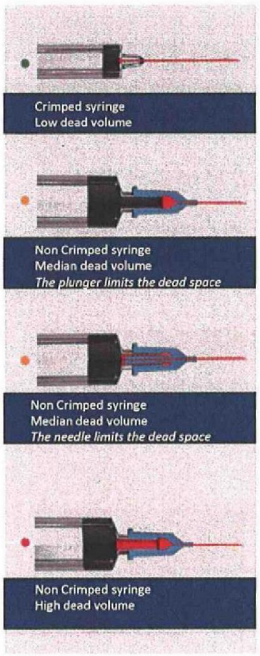
STERILE HYPODERMIC 1 ML SYRINGE WITH LOW DEAD VOLUME

Benefits of VPEX low dead volume syringe

LESS WASTE

The **VPEX** Solutions low dead volume syringes are more economical and more reliable than other types of non crimped needle. The dead volume of these syringes is 0,0025 ml, this is why we call them low dead syringes.

All syringes have a dead volume. It corresponds to the volume left in the syringe once the plunger is fully depressed.



Considering the procurement difficulties encountered during the Covid19 vaccination campaign, it is necessary to avoid vaccine wastage in order to vaccinate the greatest number of people.

A vial of Pfizer vaccine provides for the injection of 5 doses whereas in theory, it would be possible to do 6 and even 7. In fact, there is always a small amount of product left in the syringe and in the needle. This is what we call the *dead volume*.

WHEN USING THE VPEX LOW DEAD VOLUME SYRINGE, 6 DOSES ARE GUARANTEED AND 7 DOSES ARE POSSIBLE IF THE INJECTIONS ARE PROPERLY DONE.

Tests have shown that the dead space of a syringe is a risk factor for viral transmission. The World Health Organization (WHO) and UNAIDS recommend the use of low dead space syringes. The survival of the viruses inside these syringes is less than their survival in other syringes. These syringes are always preferred.

Using a syringe with a crimped needle limits handling during preparation before injection (reconstitution, insertion of the needle...) and saves precious time.

TIME SAVING

LESS PACKAGING

Using a syringe with a crimped needle limits eco-friendly. One packaging for the entire product and not one packaging for each component of a traditional syringe.

The beveled needle is preferred for patient comfort. It allows optimal penetration and avoids any punching effect which makes the injection less painful.

LESS PAIN

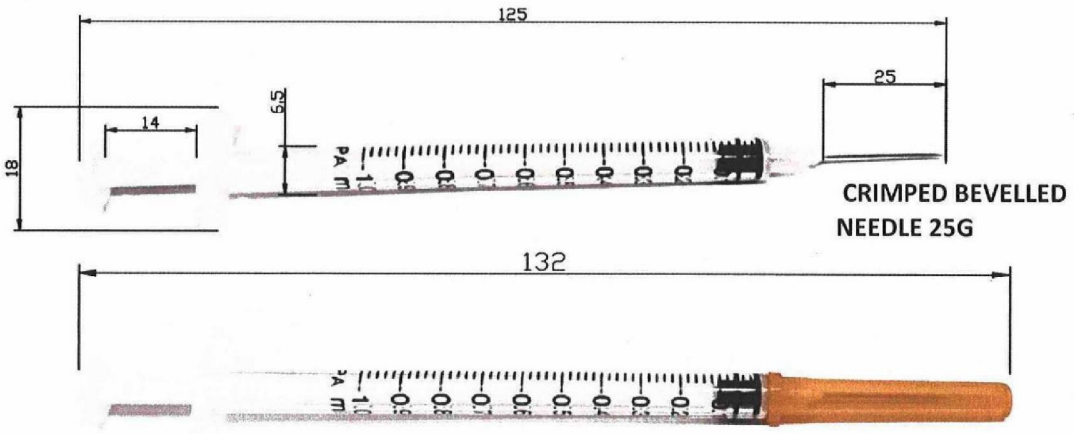
VPEX SOLUTIONS
120 rue Jean Jaurès 92300 Levallois-Perret
Tél. : 01 87 44 66 66 Fax : 01 43 96 80 10
Site : www.vpex.fr

Sas au capital de 12 000 euros - RCS Creteil B850 173 725 000 27
SIRET 850 173 725 00019 - N° TVA FR 83850173725
IBAN FR76 3006 6109 0300 0200 7360 451 BIC CMCIFRPP
FR85017372500019 DIRECTION GENERALE DES DOUANES
ET DROITS INDIRECTS N° 13930*01

USAGE FEATURES

The **VPEX** Solutions Sterile Hypodermic 1 ml Syringe with Needle for Single Use is intended to be used for medical purposes to inject medicine into the body.

- The transparent barrel of the syringe is ideal for controlling its contents
- The indelible black graduation per 0.02 ml allows an accurate reading and a perfect dosage
- A sealing ring prevents loss of medication
- Smooth sliding of the plunger ensures uniform injection without jerking or pain
- Tuberculin syringes are always fitted with a crimped, bevelled needle.



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USAGE FEATURES

1 Usage features*		
The Sterile Hypodermic 1 ml Syringe with Needle for Single Use is intended to be used for medical purposes to inject medicine into the body. **: Product features may vary depending on the intended use and usage of the product.*		
1.1	Recommended usage period :	transient
1.2	Usage	Invasive
1.3	Ergonomical features	Perfect sealing. Easy and regular sliding of the plunger. No air leakage through gasket and end piece. No dead space
1.4	Patient and user safety	The product is for single use only and required warnings about the reuse of the product.
2 Product range		
2.1	Volume	1ML
2.2	Barrel Marking Specs	0,02ML
2.3	Dead space volume	No dead space with mounting needle
2.4	Nozzle/Tip Type and Syringe Configuration	Barrel, Plunger, Plunger Stopper (Gasket)
2.5	Barrel transparency	yes
2.6	Length (mm)	86
2.7	Diameter (mm)	6.50
2.8	Operation mode	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.
2.9	Graduation Legibility	Legible
2.10	Hypodermic needle	25G ; 1 ->25mm
2.11	Needle Cap Color	Transparent and colorless
2.12	Needle Hub Color	Transparent and with above color
2.13	Needle tip configuration	Bevel needle
2.14	Components	Protective cap, needle, needle hub, adhesive, silicone oil
3 Product components		
3.1	Barrel Material	PP – Polypropylene
3.2	Plunger Material	PP – Polypropylene
3.3	Plunger Stopper (Gasket) Material	Isoprene rubber, Latex free
3.4	Lubricant composition	Silicone oil
3.5	Protective cap material	PP – Polypropylene
3.6	Adhesive material	epoxy resin
3.7	Needle and Hub Material	Needle: stainless steel, SS304 Hub: PP-Polypropylene
4 Regulatory Information		
4.1	Related Directive	93/42/EEC Medical Device Directive
4.2	Risk Class and Rule	IIa, Rule 6

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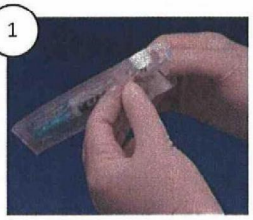
ET DROITS INDIRECTS N° 13930*01

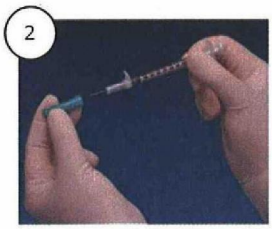
USER GUIDE

1



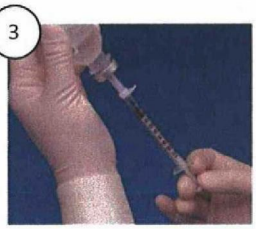
Open the sterile blister.

2



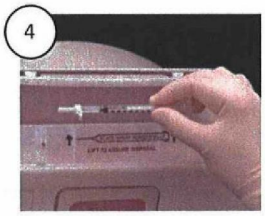
Remove the protective cap

3



Prepare the injection and perform the injection to the patient according to the protocols proper to your healthcare establishment.

4



After use, place it in a DASRI container

Note to doctors, health professionals and nurses :

IMPORTANT :Vpex sterile hypodermic syringe is for single use only. Please refer to the product leaflet to obtain complete instructions and have all the details about indications, contraindications, warnings, precautions and important information for a proper use.

Medical Device- Classe IIa – Single use hypodermic syringe – Notified organism TUV 0123 –
Manufacturer : HUNAN Pingan CN – represented in Europe by Shanghai international Holding Corp Hunan Pingan : N°8 Industry AVE Economic Dvelopment zone Li County 415500 Changde Hunan Province
Exclusively distributed by VPEX Solutions, 120 rue Jean Jaurès 92300 LEVALLOIS PERRET

CONDITIONS AND CONTACT

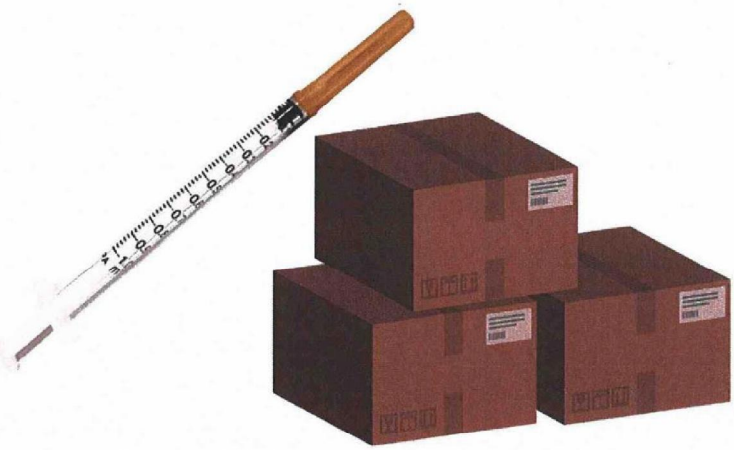
VPEX Solutions Sterile Hypodermic 1 ml Syringe with Needle for Single

Use is delivered by boxes of 3600 units (100 units per package)

CIF price : 0.39€/unit

Delivery time : please contact us

Contact : julien@vpex.fr



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IBAN FR76 3006 6109 0300 0200 7360 451 BIC CMCIFRPP
FR8501737250019 DIRECTION GENERALE DES DOUANES
ET DROITS INDIRECTS N° 13930*01

VPEX
SOLUTIONS

ANNEX
TEST REPORT

TEST REPORT

LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS
LABORATOIRE DE TRAPPES
29 avenue Roger Hennequin - 78197 TRAPPES CEDEX
Tél : 01 30 69 10 00 - Fax : 01 30 69 12 34

TEST REPORT

Delivered to	**SAS VAP EXPRESS** 120 RUE JEAN JAURES 92300 LEVALLOIS-PERRET FRANCE
Date and reference of the order	**08/02/2021 Agreement N° DEV2101818-V1**
Object	Verification tests for the maximum number of samples in distilled water and physiological serum
Document reference	Test report identified as P209731/DEC1
Reference, identification of the sample and informations	Sterile Hypodermic syringes for Single Use 1 mL/cc 25G/1"

Laboratoire national de métrologie et d'essais • Etablissement public à caractère industriel et commercial
Siège social : 1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 - Fax : 01 40 43 37 37
info@lne.fr • lne.fr • RCS Paris 313 320 244 - NAF : 7120B - TVA : FR 92 313 320 244

VPEX SOLUTIONS
120 rue Jean Jaurès 92300 Levallois-Perret
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IBAN FR76 3006 6109 0300 0200 7360 451 BIC CMCIFRPP
FR85017372500019 DIRECTION GENERALE DES DOUANES
ET DROITS INDIRECTS N° 13930*01

TEST REPORT

1. PURPOSE OF THE TEST

The National Metrology and Testing Laboratory (LNE) was requested by the company VAP EXPRESS to carry out verification tests of the maximum number of samples of 0.3 mL in a flask containing 2.25 mL of distilled water and physiological serum.

These tests follow the feasibility study to verify the maximum number of samples of 0.3 mL in a bottle containing 2.25 mL presented in the document identified P209731 / DEC1.

2. DESCRIPTION OF THE SAMPLE

To carry out these tests, the company VAP EXPRESS provided LNE with the following samples:

- Manufacturer: Hunan Pingan Medical Technology Co, Ltd
- Reference: Sterile Hypodermic syringes for Single Use 1 ml / cc 25G / 1 ' '
- Lot: 20210122
- Date of Manufacture: 22/01/2021
- Expiration Date: 21/01/2024
- Nominal volume : 1 ml
- Quantity received: 20
- Quantity testes: 14

- Quantité soumise à essai : 14

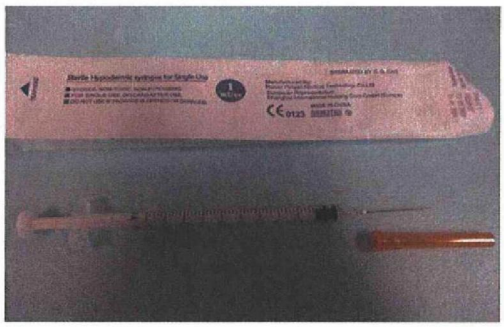

Fig. 1. Received samples

These samples are identified P209905 / 1 to 14.

These samples were received at LNE on 09/02/2021.

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*1 Information provided by the applicant

TEST REPORT

3. TEST CONDITIONS

3.1. Principle

The test consists of taking 7 samples of 0.3 mL with 7 different syringes in a flask containing 2.25 mL of distilled water (density of distilled water: 1000 kg / m3) and physiological serum with a concentration 0.9% NaCl (density of physiological saline: 1,006 kg / m3) 2.

The physiological serum used for these tests is as follows:
- Reference: Gilbert Healthcare NaCl 0.9% [illegible]
- Batch number: G210173
- Expiration date: 03/2023
- Packaging: 5 mL ampoules

Note: The feasibility study described in the report identified P209731 / DEC1 involved 6 samples in the liquid. The tests presented in this report are based on 7 samples given that the volume remaining in the vial after 6 samples is sufficient to carry out a 7th sample of 0.3 mL.

3.2 OPERATING MODE

The different stages of the test are listed below:

- Weigh the empty bottle.

- Place 2.25 mL of distilled water or psychological serum in the bottle.
Weigh the bottle again filled with water or physiological serum

- Weigh an empty syringe. With this syringe, withdraw 0.3 mL of water or serum, then weigh the syringe again.

- Repeat the last point 6 times, for a total of 7 samples. Use a new syringe for each sample.

- Weigh the bottle after the 7 samples.

- Determine the volume of distilled water or physiological serum remaining in the bottle by making the difference between the mass of the empty bottle and the mass of the bottle after the 7 Specimens.

- Determine the actual volume withdrawn with each syringe by differentiating between the mass of the syringe before and after sampling.

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*The density of the physiological saline (0.9% NaCl) was measured before the tests. See §5 of this report.

TEST REPORT

Photos are shown below to illustrate the method described above:

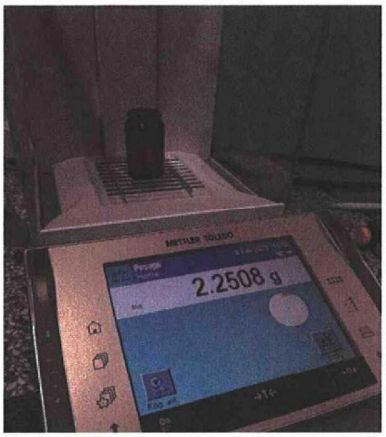

Fig. 2. Weighing of distilled water before sampling

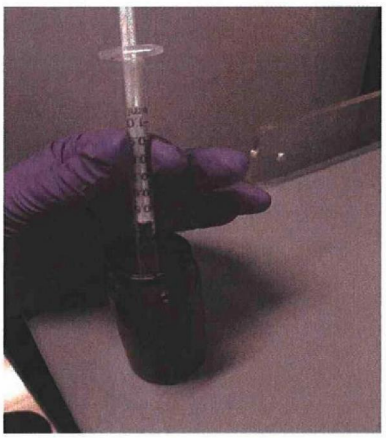

Fig. 3. Withdrawal of 0.3 ml of water using a syringe with a pre-assembled needle

TEST REPORT

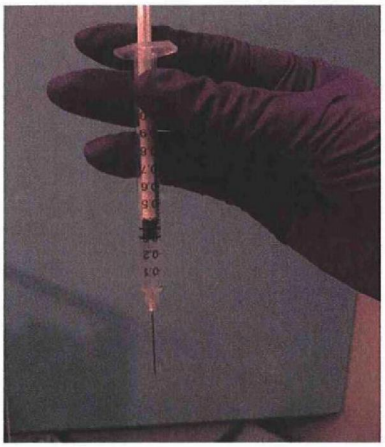

Fig. 4. Volume of 0.3 ml of water in the syringe

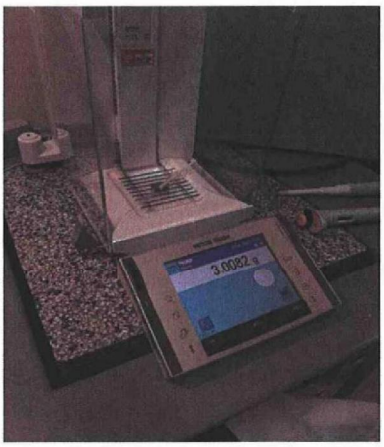

Fig. 5. Weighing with a dry syringe

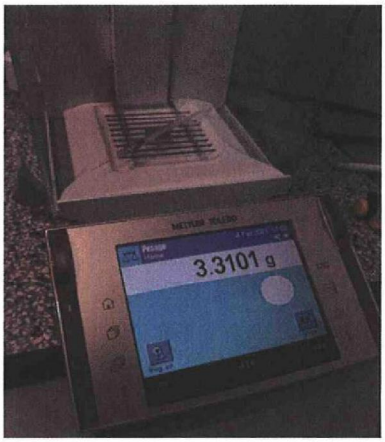

Fig. 6. **Weighing of a syringe after sampling 0.3 ml of water**

3.3 Samplings

3 tests were carried out (7 samples per test). 7 samples were tested by reference.

3.4 Equipment

- Balance with a resolution of 0.1 mg, identified 1036335
- Thermo-hygrometer, identified 1036720

The document continues on the next page

TEST REPORT

4. SAMPLING PLAN

The sampling plan followed for these tests is as follows:

	Tests to verify the maximum number of samples with distilled water	Tests to verify the maximum number of samples with physiological serum
LNE reference samplings	P209905/1 TO 7	P209905/8 TO 14

5. DENSITY MEASUREMENTS ON THE PHYSIOLOGICAL SERUM

To determine the density of physiological serum, three weighing measurements were performed in a temperature-controlled laboratory room (23 ± 5 ° C) using the cut flask method.

These measurements were carried out on 02/09/2021. The results of these measurements are presented below:

	Measure n°1	Measure n°2	Measure n°3	Average	STANDARD DEVIATION
Volumic mass (kg/m^3)	1006	1009	1003	**1006**	3,2

The document continues on the next page

TEST REPORT

6. RESULTS

The tests have been carried out from 10/02 to 11/02/2021

6.1. MAXIMUM NUMBER OF SAMPLES VERIFICATION TESTS

6.1.1. Tests with distilled water

Test n°1

Initial volume of distilled water (mL) :	2,2503

Sampling n°	Empty syringe mass (g)	Syringe with 0,3 ml (g)	Real volume withdrawn (ml)
1	2,9118	3,2106	0,2988
2	3,0439	3,3441	0,3002
3	3,0116	3,3112	0,2996
4	3,0215	3,3204	0,2989
5	2,9624	3,2597	0,2973
6	3,0087	3,3067	0,2980
7	3,0128	3,3158	0,3030
AVERAGE	**2,9961**	**3,2955**	**0,2994**
MINIMUM	**2,9118**	**3,2106**	**0,2973**
MAXIMUM	**3,0439**	**3,3441**	**0,3030**
STANDARD DEVIATION	**0,0444**	**0,0452**	**0,0019**

Volume of distilled water after the 7 samples (mL) :	0,1070

The document continues on the next page

TEST REPORT

Test n°2

Initial volume of distilled water (mL):	2,2508

Sampling n°	Empty syringe mass (g)	Syringe with 0,3 ml (g)	Real volume withdrawn (ml)
1	2,9104	3,2142	0,3038
2	3,0436	3,3419	0,2983
3	3,0089	3,3083	0,2994
4	3,0198	3,3260	0,3062
5	2,9603	3,2530	0,2927
6	3,0064	3,3117	0,3053
7	3,0109	3,3091	0,2982
AVERAGE	**2,9943**	**3,2949**	**0,3006**
MINIMUM	**2,9104**	**3,2142**	**0,2927**
MAXIMUM	**3,0436**	**3,3419**	**0,3062**
STANDARD DEVIATION	**0,0446**	**0,0449**	**0,0048**

Volume of distilled water after the 7 samples (mL) :	0,0979

Test n°3

Initial volume of distilled water (mL):	2,2500

Sampling n°	Empty syringe mass (g)	Syringe with 0,3 ml (g)	Real volume withdrawn (ml)
1	2,9106	3,2169	0,3063
2	3,0433	3,3491	0,3058
3	3,0090	3,3188	0,3098
4	3,0204	3,3262	0,3058
5	2,9601	3,2581	0,2980
6	3,0061	3,3045	0,2984
7	3,0107	3,3107	0,3000
AVERAGE	**2,9943**	**3,2978**	**0,3034**
MINIMUM	**2,9106**	**3,2169**	**0,2980**
MAXIMUM	**3,0433**	**3,3491**	**0,3098**
STANDARD DEVIATION	**0,0445**	**0,0451**	**0,0046**

Volume of distilled water after the 7 samples (mL) :	0,1013

TEST REPORT

6.1.2. Test with physiological serum

Test n°1

Initial volume of physiological serum (mL):	2,2502

Sampling n°	Empty syringe mass (g)	Syringe with 0,3 ml (g)	Real volume withdrawn (ml)
1	2,9105	3,2196	0,3073
2	3,0433	3,3426	0,2975
3	3,0090	3,3190	0,3082
4	3,0202	3,3294	0,3074
5	2,9604	3,2637	0,3015
6	3,0065	3,3154	0,3071
7	3,0106	3,3130	0,3006
AVERAGE	**2,9944**	**3,3004**	**0,3042**
MINIMUM	**2,9105**	**3,2196**	**0,2975**
MAXIMUM	**3,0433**	**3,3426**	**0,3082**
STANDARD DEVIATION	**0,0445**	**0,0433**	**0,0042**

Volume of physiological serum after the 7 samples (mL) :	0,1109

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TEST REPORT

Test n°2

Initial volume of physiological serum (mL):	2,2498

Sampling n°	Empty syringe mass (g)	Syringe with 0,3 ml (g)	Real volume withdrawn (ml)
1	3,0220	3,3345	0,3106
2	2,9550	3,2624	0,3056
3	3,0402	3,3422	0,3002
4	3,0000	3,3103	0,3084
5	2,9962	3,2986	0,3006
6	3,0266	3,3382	0,3097
7	2,9224	3,2310	0,3068
AVERAGE	**2,9946**	**3,3025**	**0,3060**
MINIMUM	**2,9224**	**3,2310**	**0,3002**
MAXIMUM	**3,0402**	**3,3422**	**0,3106**
STANDARD DEVIATION	**0,0422**	**0,0422**	**0,0042**

Volume of physiological serum after the 7 samples (mL) :	0,1036

Test n°3

Initial volume of physiological serum (mL):	2,2503

Sampling n°	Empty syringe mass (g)	Syringe with 0,3 ml (g)	Real volume withdrawn (ml)
1	3,0208	3,3330	0,3103
2	2,9534	3,2699	0,3146
3	3,0382	3,3524	0,3123
4	2,9985	3,3115	0,3111
5	2,9946	3,3056	0,3091
6	3,0320	3,3454	0,3115
7	2,9211	3,2381	0,3151
AVERAGE	**2,9941**	**3,3080**	**0,3120**
MINIMUM	**2,9211**	**3,2381**	**0,3091**
MAXIMUM	**3,0382**	**3,3524**	**0,3151**
STANDARD DEVIATION	**0,0430**	**0,0415**	**0,0022**

Volume of physiological serum after the 7 samples (mL) :	0,0519

TEST REPORT

7. CONCLUSIONS ON TEST RESULTS

7.1. MAXIMUM NUMBER OF SAMPLES VERIFICATION TESTS

7.1.1. Test with distilled water :

The tests to verify the maximum number of samples on syringes with pre-assembled needles bring the following conclusions (mean values):

Test n°	Empty syringe mass (g)	Syringe with 0,3 ml (g)	Real volume withdrawn (ml)	Initial volume (ml)	Volume after the 7 samples (ml)
1	2,9961	3,2955	0,2994	2,2503	0,107
2	2,9943	3,2949	0,3006	2,2508	0,0979
3	2,9943	3,2978	0,3034	2,25	0,1013
AVERAGE	**2,9949**	**3,2960**	**0,3011**	**2,2504**	**0,1021**
MINIMUM	**2,9943**	**3,2949**	**0,2994**	**2,2500**	**0,0979**
MAXIMUM	**2,9961**	**3,2978**	**0,3034**	**2,2508**	**0,1070**
STANDARD DEVIATION	**0,0010**	**0,0015**	**0,0021**	**0,0004**	**0,0046**

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TEST REPORT

7.1.2. Test with physiological serum :

The tests to verify the maximum number of samples on syringes with pre-assembled needles bring the following conclusions (mean values):

Test n°	Empty syringe mass (g)	Syringe with 0,3 ml (g)	Real volume withdrawn (ml)	Initial volume (ml)	Volume after the 7 samples (ml)
1	2,9944	3,3004	0,3042	2,25020	0,11093
2	2,9946	3,3025	0,3060	2,24980	0,10358
3	2,9941	3,3080	0,3120	2,25030	0,05189
AVERAGE	**2,9944**	**3,3036**	**0,3074**	**2,2501**	**0,0888**
MINIMUM	**2,9941**	**3,3004**	**0,3042**	**2,2498**	**0,0519**
MAXIMUM	**2,9946**	**3,3080**	**0,3120**	**2,2503**	**0,1109**
STANDARD DEVIATION	**0,0003**	**0,0039**	**0,0041**	**0,0003**	**0,0322**

Trappes, le

Head of Department

Medical and CE Marking department

Signature numérique de CORNILLON Thibaut
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Thibaut CORNILLON

The results mentioned are only applicable to samples, products or materials submitted to LNE and as they document.

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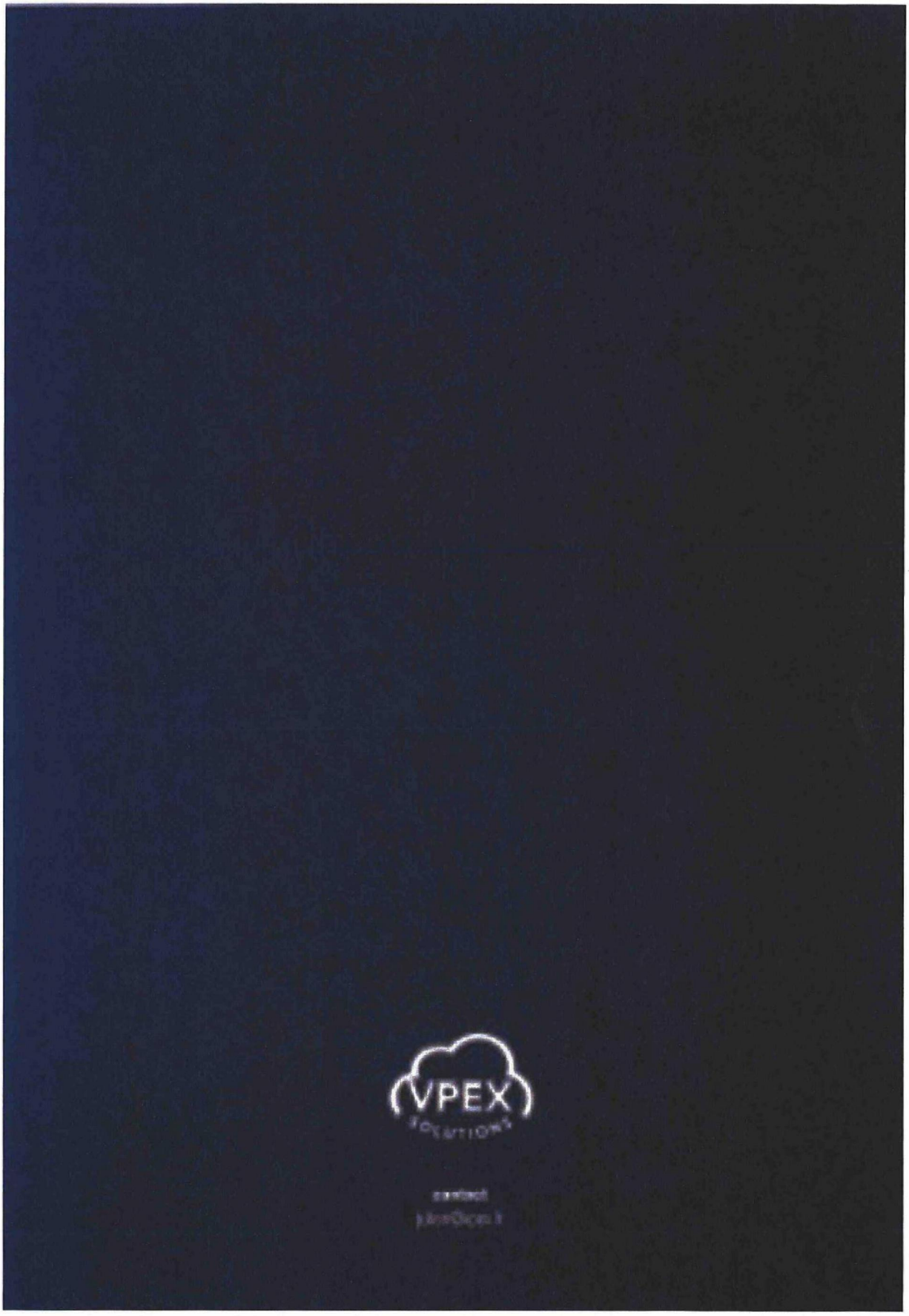
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