

REPORT OF ANALYSIS No. 136987/21/JSHR/Z2

Replaces Report of Analysis No. 136987/21/JSHR of 2021-04-14

Client ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU		Sample description (according to declaration of Client) DEZINFECTANT UNIVERSAL "BIO-DEZ"	
Sample received: 2021-03-18		Sample quantity: 2 pcs x 1 L	
Analysis completed (the date of performance of the laboratory activity): 2021-04-14		Production date: 26.01.2021	
Report dated: 2021-07-27		Expiration date: 26.01.2024	
		Sampling date: 22.02.2021	
		Sample temperature: 15°C	
		Reception hour: 15:00	
		Responsible for sampling: Crestinov Alexandr	
		Sample condition with no objections	
		Order of 2021-03-09	
		The samples were delivered by Client	

Test	Method	Unit	Result
* Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2) ¹⁾	PN-EN 1500:2013-07		The preparation has bactericidal effect against transient microorganisms used in the hygienic procedure of hand disinfection - a single rubbing of 3ml of the preparation for 60 seconds.

¹⁾ The results of the analysis in attachment No 1 to the report of analysis.

Identification of the change: test result

THE END OF THE REPORT

Authorized by:

Approved by: Hanna Wachowska, Laboratory Director (Approved with electronic signature)

Laboratory: Tychy 43-100, Goździków 1

The results relate to the analysed samples only. Unless otherwise specified given expanded measurement uncertainty was estimated for the coverage factor $k=2$ at 95% confidence level. Sampling uncertainty has not been taken into consideration. Unless otherwise specified when conformity is stated J.S. Hamilton Poland Sp. z o.o. applies the simple acceptance decision rule in accordance with ILAC-G8:09/2019. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on www.hamilton.com.pl

* Test method accredited; # Test performed by external provider

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Form PO-10/02a of 20.01.2020

J.S. HAMILTON POLAND Sp. z o.o.**TESTING LABORATORY**

ul. Chwaszczyńska 180, 81-571 Gdynia, Poland, tel. +48 58 766 99 00



ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 136987/21/JSR/Z2

A) IDENTIFICATION OF THE SAMPLE:	
Name of the product	DEZINFECTANT UNIVERSAL "BIO-DEZ" Sample quantity: 2 pcs x 1 L Production date: 26.01.2021 Expiration date: 26.01.2024 Sampling date: 22.02.2021 Sample temperature: 15°C Reception hour: 15:00 Responsible for sampling: Crestinov Alexandr
The active substance	Ethyl alcohol 72-76% CAS 64-17-5 CE 200-578-6 Benzalkonium chloride 0,024-0,029% CAS 68424-85-1 CE 270-325-2 Methylthioninium chloride 0,00024% CAS 61-73-4 and 200-515-2
B) TEST METHOD :	
Method	EN 1500:2013 Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2)
Neutralizer	Polysorbate 80 30 g/l, saponine 30g/l, histidine 1g/l, cysteine 1g/l
C) EXPERIMENTAL CONDITIONS:	
Product test concentrations (%V/V)	100%
Test temperature	20°C
Contact time	3ml of the preparation for 60s
Incubation temperature	36±1 °C
Test-organism	<i>E. coli</i> K12 NCTC 10538

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director (*Approved with qualified electronic signature*)This enclosure is an inseparable part of the report of analysis and cannot be reproduced partially without a priori written consent of J.S. Hamilton Poland Sp. z o.o.
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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 136987/21/JSR/Z2

Table 1. PROCEDURE FOR REFERENCE HYGIENIC HANDRUB

PRODUCT: Standard 2-propanol 60% (V/V)

TEST ORGANISM: *E. coli* K12 NCTC 10538

NUMBER IN CONTAMINATION FLUID: $2,4 \times 10^8$ cfu/ml

volunteer		number of cfu per plate from dilution 10x							Reduction	
Nr	Hand left/right	prevalues			postvalues					
		x10 ⁻⁴	x10 ⁻⁵	log x	x10 ⁰	x10 ⁻¹	x 10 ⁻²	log y		log z
1	l	288	29		61	7	0			
	r	247	22	6,42	33	3	0	1,65	4,77	
2	l	167	17		51	5	0			
	r	291	28	5,81	36	4	0	1,63	4,18	
3	l	175	11		42	5	0			
	r	275	25	6,33	29	2	0	1,54	4,79	
4	l	220	21		30	3	0			
	r	192	19	6,31	68	6	0	1,65	4,66	
5	l	164	15		37	3	0			
	r	301	33	6,35	52	5	0	1,64	4,71	
6	l	200	20		23	2	0			
	r	198	18	6,30	37	4	0	1,46	4,83	
7	l	287	22		60	6	0			
	r	288	29	6,45	42	5	0	1,70	4,75	
8	l	298	28		31	4	0			
	r	213	21	6,40	58	5	0	1,63	4,77	
9	l	283	23		34	3	0			
	r	311	33	5,96	51	5	0	1,62	4,34	
10	l	313	32		53	6	0			
	r	251	25	6,45	36	4	0	1,65	4,80	
11	l	175	18		54	5	0			
	r	295	22	6,35	47	3	0	1,69	4,66	
12	l	183	19		72	7	0			
	r	171	17	5,74	36	4	0	1,71	4,03	
13	l	206	22		29	2	0			
	r	317	33	6,41	49	5	0	1,57	4,84	
14	l	295	28		55	6	0			
	r	279	25	6,45	64	7	0	1,78	4,68	
15	l	248	22		72	7	0			
	r	256	26	6,40	66	6	0	1,84	4,56	
16	l	301	31		46	5	0			
	r	261	26	6,45	27	3	0	1,55	4,90	
17	l	259	24		41	4	0			
	r	271	28	6,42	22	1	0	1,47	4,96	
18	l	259	22		61	6	0			
	r	288	23	6,43	33	3	0	1,65	4,78	
19	l	223	21		35	4	0			
	r	205	20	6,33	45	5	0	1,60	4,72	
20	l	297	28		54	6	0			
	r	257	24	5,90	28	3	0	1,59	4,31	
x _{sr}				6,28					1,63	4,65
s				0,23					0,09	0,25

log x-logarithm of the average value of the initial left and right hand

log y-logarithm of the average value of the final left and right hand

log z-logarithm reduction

x_{sr} - overall average of log x, log y, log z

Date: 27.07.2021

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Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

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Table 2. HYGIENIC HANDRUB PROCEDURE WITH THE PRODUCT

PRODUCT P 136987/21/JSR

TEST ORGANISM: *E. coli* K12 NCTC 10538

NUMBER IN CONTAMINATION FLUID: $2,4 \times 10^8$ cfu/ml

volunteer		number of cfu per plate from dilution 10x							Reduction
Nr	Hand left/right	prevalues			postvalues				
		x10 ⁻⁴	x10 ⁻⁵	log x	x10 ⁰	x10 ⁻¹	x 10 ⁻²	log y	
1	l	132	14		103	11	1		
	r	224	21	6,24	92	9	0	1,98	4,26
2	l	>330	125		89	7	0		
	r	304	31	6,27	78	4	0	1,68	4,59
3	l	144	15		97	9	0		
	r	132	11	6,14	78	5	0	1,93	4,21
4	l	328	34		87	8	0		
	r	>330	85	6,20	99	9	0	1,89	4,32
5	l	164	11		116	11	2		
	r	132	12	6,16	99	8	0	2,03	4,13
6	l	>330	121		61	3	0		
	r	320	32	6,27	83	9	0	1,67	4,60
7	l	328	33		61	4	0		
	r	288	29	6,49	71	7	0	1,81	4,68
8	l	>330	58		91	9	0		
	r	>330	22	5,51	72	6	0	1,82	3,69
9	l	336	36		79	8	0		
	r	>330	21	5,90	106	12	2	1,96	3,94
10	l	296	28		74	7	0		
	r	>330	41	6,02	85	9	0	1,90	4,12
11	l	228	21		93	8	0		
	r	104	11	6,19	80	5	0	1,93	4,26
12	l	>330	48		107	11	1		
	r	200	20	5,97	94	9	0	1,98	4,00
13	l	248	25		112	14	2		
	r	212	22	6,36	113	11	1	2,06	4,31
14	l	>330	48		89	8	0		
	r	255	22	6,02	91	9	0	1,95	4,07
15	l	278	28		99	7	0		
	r	169	17	6,34	67	6	0	1,77	4,57
16	l	178	11		104	11	1		
	r	255	25	6,32	69	7	0	1,93	4,39
17	l	274	28		79	8	0		
	r	231	24	6,40	107	12	2	1,97	4,44
18	l	225	22		92	9	0		
	r	183	19	6,31	66	7	0	1,89	4,42
19	l	199	17		53	5	0		
	r	252	23	6,35	89	8	0	1,83	4,51
20	l	266	22		97	9	0		
	r	231	21	6,39	68	7	0	1,91	4,48
x _{śr}				6,19				1,89	4,30
s				0,22				0,10	0,25

log x-logarithm of the average value of the initial left and right hand

log y-logarithm of the average value of the final left and right hand

log z-logarithm reduction

x_{śr}- overall average of log x, log y, log z

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Table 3. LIST OF COMPUTED IG VALUES AND IG REDUCTIONS

volunteer		R 2-propanol 60% (V/V)			P		
Nr		log x	log y	log z	log x	log y	log z
1	R-P	6,42	1,65	4,77	6,24	1,99	4,25
2	R-P	5,81	1,63	4,18	6,27	1,91	4,36
3	R-P	6,33	1,54	4,79	6,14	1,93	4,21
4	R-P	6,31	1,65	4,66	6,20	1,96	4,24
5	R-P	6,35	1,64	4,71	6,16	2,03	4,13
6	P-R	6,30	1,46	4,83	6,27	1,84	4,43
7	P-R	6,45	1,70	4,75	6,49	1,81	4,68
8	P-R	6,40	1,63	4,77	5,51	1,90	3,61
9	P-R	5,96	1,62	4,34	5,90	1,96	3,94
10	P-R	6,45	1,65	4,80	6,02	1,90	4,12
11	R-P	6,35	1,69	4,66	6,19	1,93	4,26
12	R-P	5,74	1,71	4,03	5,97	2,00	3,97
13	R-P	6,41	1,57	4,84	6,36	2,06	4,31
14	R-P	6,45	1,78	4,68	6,02	1,95	4,07
15	R-P	6,40	1,84	4,56	6,34	1,90	4,43
16	P-R	6,45	1,55	4,90	6,32	1,93	4,39
17	P-R	6,42	1,47	4,96	6,40	1,97	4,44
18	P-R	6,43	1,65	4,78	6,31	1,89	4,42
19	P-R	6,33	1,60	4,72	6,35	1,83	4,51
20	P-R	5,90	1,59	4,31	6,39	1,91	4,48
X ₂₀		6,28	1,63	4,65	6,19	1,93	4,26
X10(R-P)		6,26	1,67	4,59	6,19	1,97	4,22
X10 (P-R)		6,31	1,59	4,72	6,20	1,90	4,30

Criteria:

 $R_s (R-P) = 4,59 - 4,22 = 0,37$
 $R_s (P-R) = 4,72 - 4,30 = 0,42$
 $Abs = 0,37 - 0,42 = -0,05 < 2$
 $\log x(R) = 6,28 > 5$
 $\log x(P) = 6,19 > 5$
 $\log z (P), \log z (R) > 3$

Validation conditions of neutralizer and methods have been satisfied

Date: 27.07.2021

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Table 4. COMPUTATION OF INDIVIDUAL DIFFERENCES OF lg R-P

volunteer	log RF		difference R-P	difference high to low	Range +/-
	R	P			
1	4,77	4,25	0,52	1,16	1
2	4,18	4,36	-0,18	0,68	2
3	4,79	4,21	0,59	0,61	3
4	4,66	4,24	0,42	0,59	4
5	4,71	4,13	0,58	0,58	5
6	4,83	4,43	0,40	0,53	6
7	4,75	4,68	0,07	0,52	7
8	4,77	3,61	1,16	0,52	8
9	4,34	3,94	0,40	0,51	9
10	4,80	4,12	0,68	0,42	10
11	4,66	4,26	0,40	0,40	11
12	4,03	3,97	0,06	0,40	12
13	4,84	4,31	0,53	0,40	13
14	4,68	4,07	0,61	0,36	14
15	4,56	4,43	0,13	0,21	15
16	4,90	4,39	0,51	0,13	16
17	4,96	4,44	0,52	0,07	17
18	4,78	4,42	0,36	0,06	18
19	4,72	4,51	0,21	-0,17	-19
20	4,31	4,48	-0,17	-0,18	-20
sum of ranks (+): 171					
sum of ranks (-): 39					

Table 5. SORTING OF INDIVIDUAL DIFFERENCES AND COMPUTATION FOR HODGES-LEHMANN 97,5% UPPER CONFIDENCE LIMITS FOR THE DIFFERENCE IN lg BETWEEN R-P

	1,16	0,68	0,61	0,59	0,58	0,53	0,52	0,52	0,51
1	1,16								
2	0,68	0,92							
3	0,61	0,89	0,65						
4	0,59	0,87	0,63	0,60	0,59				
5	0,58	0,87	0,63	0,59	0,58	0,58			
6	0,53	0,85	0,61	0,57	0,56	0,55	0,53		
7	0,52	0,84	0,60	0,57	0,56	0,55	0,53	-0,52	
8	0,52	0,84	0,60	0,56	0,55	0,55	0,53	-0,52	-0,52
9	0,51	0,83	0,59	0,56	0,55	0,54	0,52	-0,52	-0,51
10	0,42	0,79	0,55	0,52	0,50	0,50	0,48	-0,47	-0,47
11	0,40	0,78	0,54	0,51	0,49	0,49	0,47	-0,46	-0,46
12	0,40	0,78	0,54	0,51	0,49	0,49	0,47	-0,46	-0,46
13	0,40	0,78	0,54	0,50	0,49	0,49	0,47	-0,46	
14	0,36	0,76	0,52	0,49	0,47	0,47	0,45		
15	0,21	0,69	0,45	0,41	0,40	0,39			
16	0,13	0,65	0,41	0,37	0,36				
17	0,07	0,62	0,38	0,34					
18	0,06	0,61	0,37						
19	-0,17	0,50							
20	-0,18								

Date: 27.07.2021

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Table 6. WILCOXON'S T-MATCHED PAIRS SIGNED-RANKS TEST:
CRITICAL VALUES LESS WITH RANG SUM (+) OR (-) AT DIFFERENT LEVELS OF SIGNIFICANCE

n	one-sided level of significance		
	0,05	0,025	0,01
18	47	40	32
19	53	46	27
20	60	52	43
21	68	59	49
22	75	66	56

For the designated level of significance 0,025 for n=20 the value read from the table 6 is 52.

Hence $c = 52 + 1 = 53$.

For the distribution of 53 Table 5 assigns a value of 0,55 which is less than the agreed inferiority margin of 0,6.

Therefore, the hypothesis of inferiority of PP compared to the reference RP is rejected.

The test preparation (PP) is non-inferior to RP.

Date: 27.07.2021

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RAPORT DE INCERCARE NR. 79165/22/ROBCH/Z1

Inlocuieste Raportul de Incercare Nr. 79165/22/ROBCH din 07.03.2022

Client ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU		Numărul eșantionului: Sample number Descriere obiect de incercat (conform cu declaratia Clientului) Dezinfectant Universal "Bio-Dez" Lot/Batch: - Production date: - Expiration date: 18.02.2025 Sampling date: 18.02.2022 Sampling quantity: 1x 500ml Sample temperature: 20°C Reception hour: 12:30 Responsible for sampling: Crestinov Alexandr Sample condition with no objections
Data primirii obiectului de incercat:	07.03.2022	Comanda din 07.03.2022 Probele au fost prelevate si livrate de catre Client.
Data finalizarii incercarii:	08.09.2022	
Data eliberarii raportului:	08.09.2022	

Parametrii de testare	Metoda de testare	Unitate de masura	Rezultat
# * Chemical disinfectants and antiseptics. Surgical hand disinfection. Test method and requirements (phase 2, step 2)	EN 12791:2016+A1:2017		Test method performed by the subcontractor; the results are taken in full from the test report No S68/2022-1, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborat de: Mariana Ilinca, Sef Laborator Microbiologie
 Autorizat de: Mariana Ilinca, Sef Laborator Microbiologie
 Aprobat de catre: Alina-Roxana Mihai, General Manager (Aprobat cu semnatura electronica)

Laborator: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevarii probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de incredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solicitati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Metoda de testare acreditata # Test efectuat de catre subcontractor
 o Incercari neacreditate

A) IDENTIFICATION OF THE SAMPLE	
Name of the product/Details about the product	Dezinfectant Universal "Bio-Dez" Date of manufacture: 18.02.2022 Manufacturer: Ecochim-Grup SRL, Petricani St 21/3, Chişinău 2059, Moldavsko Incoming date: 7.3.2022 Storing conditions: room temperature, dark area. Subject of testing: Surgical handrub - immediate effect Active ingredients: CAS: 68424-85- Alkyldimethylbenzylamoniumchloride 0.029% CAS: 64-17-5 Ethyl alcohol 73.0%
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation No. 1273 Determination of surgical hand disinfection (EN 12791:2016+A1:2017) of the product Dezinfectant Universal "Bio-Dez"	Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers SOP-M-19-00 (EN 12791:2016+A1:2017)
C) Description: Testing the efficacy of chemical disinfectants and antiseptics	
Sampling date:	18.2.2022
Sample delivered:	7.3.2022
Testing date:	16.8. - 31.8.2022
D) EXPERIMENTAL CONDITIONS	
Effect:	immediate effect
Period of analysis:	16.08.2022 - 31.08.2022
Test temperature:	20 °C ± 1 °C
Test method:	dilution neutralization method
Appearance of the product:	Blue liquid
The test concentration:	100%
The volume of the product:	2 x 7 ml
The application time:	2 x 45 s
Procedure:	handrub
The soap:	soft soap from linseed oil
Reference item:	CAS 71-23-8 1-propanol p.a., 60% (V/V)
The volume of the reference propan- 1-ol used per person: 2 x 3 ml, according to reference surgical hand disinfection procedure, the total application volume is 6 ml	
The application time:	2 x 1.5 min, according to reference surgical hand disinfection procedure, the total application time is 3 min
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Surgical hand disinfection procedure with product:	handrub procedure, immediate effect
Requirements:	The mean reduction for immediate effect of a product shall at least be not inferior to that achieved by a specified reference product (60% volume concentration of propan-1-ol). To demonstrate additionally a "sustained effect", the mean reduction for the 3 h effect of a product shall be superior to that achieved by the reference product
Test procedure:	1. Determination of the presence of microorganisms in the product 2. Determination of the prevalue – number of cfu sampled immediately before treatment from the hand 3. Determination of the postvalue – number of cfu sampled after

Laboratory: Bucharest 041914, 8 Berceni Street.

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*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 08.09.2022

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 79165/22/ROBCH

	treatment from the hand 4. Expression and interpretation of results - reduction factor – ratio of prevalue and postvalue, generally expressed by decimal logarithms
The standard:	EN 12791:2016+A1:2017 Chemical disinfectants and antiseptics – Surgical hand disinfection – Test method and requirements (phase 2/step 2) November 2017

The number of CFU in the tested product: 0 CFU/ml

Testing the efficacy of chemical disinfectant **L21229/22/JSHR** on *Pseudomonas aeruginosa* ATCC 15442

Test suspensions

N	V1	V2	lgN	lgN ₀
10 ⁻⁶	192	170		
10 ⁻⁷	27	15	8,26	7,26
$\Phi = 1,84 \times 10^8$			$8,17 \leq \lg N \leq 8,7$	$7,17 \leq \lg N_0 \leq 7,7$

Verification of methodology

Validation of suspension (N _{vo})		Method valid (C), conditions: 80 %, 90 s, distilled water, 20°C	
V _{e1}	31	V _{e1}	29
V _{e2}	60	V _{e2}	55
30 < 45,5 < 160		42 > 0,5 N _{vo}	

Testing the efficacy of chemical disinfectant **L21229/22/JSHR** on *Staphylococcus aureus* ATCC 6538

Test suspensions

N	V1	V2	lgN	lgN ₀
10 ⁻⁶	304	252		
10 ⁻⁷	20	33	8,44	7,44
$\Phi = 2,77 \times 10^8$			$8,17 < \lg N < 8,7$	$7,17 < \lg N_0 < 7,7$

Verification of methodology

Validation of suspension (N _{vo})		Method valid (C), conditions: 80 %, 90 s, distilled water, 20°C	
V _{e1}	69	V _{e1}	72
V _{e2}	53	V _{e2}	42
30 < 61 < 160		57 > 0,5 N _{vo}	

Testing the efficacy of chemical disinfectant **L21229/22/JSHR** on *Enterococcus hirae* ATCC 10541

Test suspensions

N	V1	V2	lgN	lgN ₀
10 ⁻⁶	166	192		
10 ⁻⁷	18	21	8,26	7,26
$\Phi = 1,8 \times 10^8$			$8,17 \leq \lg N \leq 8,7$	$7,17 \leq \lg N_0 \leq 7,7$

Verification of methodology

Validation of suspension (N _{vo})		Method valid (C), conditions: 80 %, 90 s, distilled water, 20°C	
V _{e1}	52	V _{e1}	46
V _{e2}	40	V _{e2}	42
30 < 46 < 160		44 > 0,5 N _{vo}	

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*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 79165/22/ROBCH

 Testing the efficacy of chemical disinfectant **L21229/22/JSHR** on *Escherichia coli* K 12 NCTC 10538

Test suspensions

N	V1	V2	lgN	lgN ₀
10 ⁻⁶	>330	>330		
10 ⁻⁷	49	33	8.61	7.61
$\Phi = 4.1 \times 10^8$			8.17 < lgN < 8.7	7.17 < lgN ₀ < 7.7

Verification of methodology

Validation of suspension (N ₀)		Method valid.(C), conditions: 80 %, 90 s, distilled water, 20°C	
V _{e1}	113	V _{e1}	103
V _{e2}	103	V _{e2}	110
30 < 108 < 160		106.5 > 0.5 N ₀	

 Testing the efficacy of chemical disinfectant **L21229/22/JSHR** on *Candida albicans* ATCC 10231

Test suspensions

N	V1	V2	lgN	lgN ₀
10 ⁻⁵	155	144		
10 ⁻⁶	17	15	7.18	6.18
$\Phi = 1.5 \times 10^7$			7.17 < lgN < 7.7	7.17 < lgN ₀ < 7.7

Verification of methodology

Validation of suspension (N ₀)		Method valid.(C), conditions: 80 %, 90 s, distilled water, 20°C	
V _{e1}	41	V _{e1}	21
V _{e2}	34	V _{e2}	28
30 < 37.5 < 160		24.5 > 0.5 N ₀	

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N₀ = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, C = the number of surviving bacteria per ml in control tests

Acceptance criteria for test results:

Only if the results of the test procedure fulfil the following requirements, they shall be accepted for further evaluation, otherwise the test shall be repeated:

- A complete set of results from at least 23, but maximum 28 volunteers shall be available. All complete sets of results shall be used for further evaluation.
- The overall means of the lg prevalues for RP and PP shall be both at least 3,50.
- The absolute difference of mean differences between lg reductions of RP and PP of group RP → PP and group PP → RP shall be less than 2,00
- All quotients of weighted mean counts between 5 and 15.

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 79165/22/ROBCH**Conclusion:**

The acceptance criteria for the test results were met.

From table in EN 12791:2016+A1:2017 of critical values for Wilcoxon's matched-pairs signed-ranks test the entry for $n = 24$ and a one sided 0.025 level of significance, the critical value of 81 is found. Hence $c = 81 + 1 = 82$. The pairwise differences are sorted in descending order. The 82nd value is 0,59. Hence the Hodges-Lehmann upper one sided 97,5% confidence limit for the difference in lg Rs between RP and PP is 0,59, which is less than the agreed inferiority margin of 0,75. Therefore the hypothesis of inferiority of PP is rejected and it can be concluded that the test preparation PP is non-inferior to RP.

The tested product:	Dezinfectant Universal "Bio-Dez"
Batch number:	Not specified
Standard:	EN 12791:2016+A1:2017
Test method:	dilution neutralization method
Effect:	immediate effect

Conditions:

Application time:	2 x 45 s
Volume of the product:	2 x 7 ml
Concentration:	100%

The tested product is suitable to be used as surgical hand disinfection.

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Volunteer	Chronological Sequence	Reference hand disinfection procedure RP					Reference handrub procedure with product PP					Difference RP - PP
		N prevalues	N postvalues	lg prevalues	lg postvalues	lg R	N prevalues	N postvalues	lg prevalues	lg postvalues	lg R	
1	RP	7,30E+04	7,90E+02	4,86	2,90	1,96	6,40E+04	7,70E+02	4,81	2,89	1,92	0,04
2	RP	7,90E+04	6,60E+03	4,90	3,82	1,08	9,00E+04	1,00E+04	4,95	4,00	0,95	0,13
3	RP	7,10E+04	1,88E+03	4,85	3,27	1,58	1,06E+05	1,20E+03	5,03	3,08	1,95	-0,37
4	RP	7,90E+04	8,50E+02	4,90	2,93	1,97	5,80E+04	1,00E+02	4,76	2,00	2,76	-0,79
5	RP	9,60E+04	9,60E+03	4,98	3,98	1,00	8,90E+04	1,12E+04	4,95	4,05	0,90	0,10
6	RP	8,50E+04	2,44E+03	4,93	3,39	1,54	1,70E+04	6,70E+03	4,23	3,83	0,40	1,14
7	RP	7,70E+04	7,10E+03	4,89	3,85	1,04	1,02E+04	2,21E+03	4,01	3,34	0,67	0,37
8	RP	6,80E+04	3,80E+02	4,83	2,58	2,25	1,29E+05	9,30E+03	5,11	3,97	1,14	1,11
9	RP	5,60E+04	4,90E+03	4,75	3,69	1,06	8,30E+04	5,10E+03	4,92	3,71	1,21	-0,15
10	RP	7,10E+04	9,90E+03	4,85	4,00	0,85	7,60E+04	9,40E+03	4,88	3,97	0,91	-0,06
11	RP	1,02E+05	1,01E+04	5,01	4,00	1,01	6,90E+04	9,30E+03	4,84	3,97	0,87	0,14
12	RP	9,40E+04	1,07E+04	4,97	4,03	0,94	1,11E+05	1,24E+04	5,05	4,09	0,96	-0,02
13	PP	7,90E+04	2,91E+03	4,90	3,46	1,44	9,80E+04	7,80E+03	4,99	3,89	1,10	0,34
14	PP	9,10E+04	6,10E+03	4,96	3,79	1,17	7,80E+04	8,00E+03	4,89	3,90	0,99	0,18
15	PP	7,50E+04	3,08E+03	4,88	3,49	1,39	1,12E+04	1,56E+03	4,05	3,19	0,86	0,53
16	PP	5,20E+04	9,30E+02	4,72	2,97	1,75	1,10E+05	2,01E+02	5,04	2,30	2,74	-0,99
17	PP	8,50E+04	6,50E+03	4,93	3,81	1,12	1,02E+05	1,23E+04	5,01	4,09	0,92	0,20
18	PP	1,06E+04	2,04E+02	4,03	2,31	1,72	6,50E+03	7,50E+02	3,81	2,88	0,93	0,79
19	PP	8,00E+04	1,10E+03	4,90	3,04	1,86	1,68E+04	4,80E+02	4,23	2,68	1,55	0,31
20	PP	1,10E+05	6,00E+03	5,04	3,78	1,26	9,90E+04	8,60E+03	5,00	3,93	1,07	0,19
21	PP	6,30E+04	2,76E+02	4,80	2,44	2,36	8,70E+04	2,86E+03	4,94	3,46	1,48	0,88
22	PP	5,50E+04	4,40E+02	4,74	2,64	2,10	5,30E+04	7,10E+03	4,72	3,85	0,87	1,23
23	PP	1,18E+05	9,70E+02	5,07	2,99	2,08	8,20E+04	6,50E+03	4,91	3,81	1,10	0,98
24	PP	1,04E+05	7,60E+02	5,02	2,88	2,14	1,16E+05	1,35E+04	5,06	4,13	0,93	1,21
Ø	Overall	7,81E+04	3,94E+03	4,86	3,34	1,52	7,34E+04	6,14E+03	4,76	3,54	1,22	
s		2,23E+04	3,62E+03	0,20	0,55	0,48	3,68E+04	4,43E+03	0,38	0,61	0,59	
n				24	24	24			24	24	24	
Ø	RP → PP			4,89	3,54	1,35			4,79	3,57	1,22	0,13
s				0,07	0,51	0,48			0,33	0,64	0,66	
n				12	12	12			12	12	12	
Ø	PP → RP			4,83	3,13	1,70			4,72	3,51	1,21	0,49
s				0,28	0,53	0,42			0,44	0,61	0,53	
n				12	12	12			12	12	12	

Sorting of individual differences and computation for Hodges-Lehman 97,5% upper confidence limits													
	Sorted differences	Mean pairwise differences (di+dij)/2											
1	1,23	1,23											
2	1,21	1,22	1,21										
3	1,14	1,19	1,18	1,14									
4	1,11	1,17	1,16	1,13	1,11								
5	0,98	1,11	1,10	1,06	1,05	0,98							
6	0,88	1,06	1,05	1,01	1,00	0,93	0,88						
7	0,79	1,01	1,00	0,97	0,95	0,89	0,84	0,79					
8	0,53	0,88	0,87	0,84	0,82	0,76	0,71	0,66	0,53				
9	0,37	0,80	0,79	0,76	0,74	0,68	0,63	0,58	0,45	0,37			
10	0,34	0,79	0,78	0,74	0,73	0,66	0,61	0,57	0,44	0,36	0,34		
11	0,31	0,77	0,76	0,73	0,71	0,65	0,60	0,55	0,42	0,34	0,33	0,31	
12	0,20	0,72	0,71	0,67	0,66	0,59	0,54	0,50	0,37	0,29	0,27	0,26	0,20
13	0,19	0,71	0,70	0,67	0,65	0,59	0,54	0,49	0,36	0,28	0,27	0,25	0,20
14	0,18	0,71	0,70	0,66	0,65	0,58	0,53	0,49	0,36	0,28	0,26	0,25	
15	0,14	0,69	0,68	0,64	0,63	0,56	0,51	0,47	0,34	0,26	0,24		
16	0,13	0,68	0,67	0,64	0,62	0,56	0,51	0,46	0,33	0,25			
17	0,10	0,67	0,66	0,62	0,61	0,54	0,49	0,45	0,32				
18	0,04	0,64	0,63	0,59	0,58	0,51	0,46	0,42					
19	-0,02	0,61	0,60	0,56	0,55	0,48	0,43						
20	-0,06	0,59	0,58	0,54	0,53	0,46							
21	-0,15	0,54	0,53	0,50	0,48								
22	-0,37	0,43	0,42	0,39									
23	-0,79	0,22	0,21										
24	-0,99	0,12											

log R = decimal log reduction; RP→PP sequence: first RP, second PP; PP→RP sequence: first PP, second RP; Ø = mean; s = standard deviation; n = number of values (volunteer)

Difference of mean Rs (RP→PP): 1,35 - 1,22 = 0,13; Difference of mean Rs (PP→RP): 1,70 - 1,21 = 0,49; Absolute difference of differences: |0,13 - 0,49| = 0,36

The median is between the 12th and 13th value: [0,20 + 0,19]/2 = 0,195

The mean pairwise differences that do not exceed the median (here: 0,195) are computed. From table in EN 12791:2016+A1:2017 of critical values for Wilcoxon's matched-pairs signed-ranks test the entry for n = 24 and a one-sided P = 0,025 level of significance, the critical value of 81 is found. Hence c = 81 + 1 =82. The pairwise differences are sorted in descending order. The 82nd value is 0,59.

Hence the Hodges-Lehmann upper one sided 97,5% confidence limit for the difference in lg Rs between RP and PP is 0,59, which is less than the agreed inferiority margin of 0,75.

Therefore the hypothesis of inferiority of PP is rejected and it can be concluded that the test preparation PP is non-inferior to RP.

Annex
raw data

EN 12791:2016+A1:2017,
immediate effect

Bio-Dez
sample S68/2022

Propan-1-ol batch No.: K52972497115, expiry date 31.12.25 60%, 2 x 3 ml, 2 x 1,5 min, immediate effect, hand disinfection procedure

Volunteer			Number of CFU per plate from dilution 10 ³					
No	Sequence	Hand (left or right)	Prevalues			Immediate postvalues		
			-1	-2	-3	0	-1	-2
1	RP → PP	l	>330	>330	<u>73</u>	>330	<u>79</u>	<14
2	RP → PP	l	>330	>330	<u>79</u>	>330	>330	<u>66</u>
3	RP → PP	l	>330	>330	<u>71</u>	>330	<u>186</u>	<u>21</u>
4	RP → PP	l	>330	>330	<u>79</u>	>330	<u>85</u>	<14
5	RP → PP	l	>330	>330	<u>96</u>	>330	>330	<u>96</u>
6	RP → PP	l	>330	>330	<u>85</u>	>330	<u>241</u>	<u>27</u>
7	RP → PP	r	>330	>330	<u>77</u>	>330	>330	<u>71</u>
8	RP → PP	r	>330	>330	<u>68</u>	>330	<u>38</u>	<14
9	RP → PP	r	>330	>330	<u>56</u>	>330	>330	<u>49</u>
10	RP → PP	r	>330	>330	<u>71</u>	>330	>330	<u>99</u>
11	RP → PP	r	>330	>330	<u>102</u>	>330	>330	<u>101</u>
12	RP → PP	r	>330	>330	<u>94</u>	>330	>330	<u>107</u>
13	PP → RP	l	>330	>330	<u>79</u>	>330	<u>292</u>	<u>28</u>
14	PP → RP	l	>330	>330	<u>91</u>	>330	>330	<u>61</u>
15	PP → RP	l	>330	>330	<u>75</u>	>330	<u>306</u>	<u>33</u>
16	PP → RP	l	>330	>330	<u>52</u>	>330	<u>93</u>	<14
17	PP → RP	l	>330	>330	<u>85</u>	>330	>330	<u>65</u>
18	PP → RP	l	>330	<u>106</u>	<14	<u>201</u>	<u>23</u>	<14
19	PP → RP	r	>330	>330	<u>80</u>	>330	<u>110</u>	<14
20	PP → RP	r	>330	>330	<u>110</u>	>330	>330	<u>60</u>
21	PP → RP	r	>330	>330	<u>63</u>	<u>269</u>	<u>35</u>	<14
22	PP → RP	r	>330	>330	<u>55</u>	>330	<u>44</u>	<14
23	PP → RP	r	>330	>330	<u>118</u>	>330	<u>97</u>	<14
24	PP → RP	r	>330	>330	<u>104</u>	>330	<u>76</u>	<14

Period of analysis: 16.8.2022 - 31.8.2022

16.8.-17.8.2022, 30.8.-31.8.2022

Prepared by: Mgr. Alena Holiková

Annex
raw data

EN 12791:2016+A1:2017,
immediate effect

Bio-Dez
sample S68/2022

Product Dezinfektant Universal "Bio-Dez" 100%, 2 x 7 ml, 2 x 45 s, immediate effect, handrub

Volunteer			Number of CFU per plate from dilution 10 ⁵					
No	Sequence	Hand (left or right)	Prevalues			Immediate postvalues		
			-1	-2	-3	0	-1	-2
1	RP → PP	r	>330	>330	<u>64</u>	>330	<u>77</u>	<14
2	RP → PP	r	>330	>330	<u>90</u>	>330	>330	<u>101</u>
3	RP → PP	r	>330	>330	<u>106</u>	>330	<u>120</u>	<14
4	RP → PP	r	>330	>330	<u>58</u>	<u>99</u>	<14	<14
5	RP → PP	r	>330	>330	<u>89</u>	>330	>330	<u>112</u>
6	RP → PP	r	>330	<u>168</u>	<u>19</u>	>330	>330	<u>67</u>
7	RP → PP	l	>330	<u>102</u>	<14	>330	<u>216</u>	<u>27</u>
8	RP → PP	l	>330	>330	<u>129</u>	>330	>330	<u>93</u>
9	RP → PP	l	>330	>330	<u>83</u>	>330	>330	<u>51</u>
10	RP → PP	l	>330	>330	<u>76</u>	>330	>330	<u>94</u>
11	RP → PP	l	>330	>330	<u>69</u>	>330	>330	<u>93</u>
12	RP → PP	l	>330	>330	<u>111</u>	>330	>330	<u>124</u>
13	PP → RP	r	>330	>330	<u>98</u>	>330	>330	<u>78</u>
14	PP → RP	r	>330	>330	<u>78</u>	>330	>330	<u>80</u>
15	PP → RP	r	>330	<u>112</u>	<14	>330	<u>156</u>	<u>16</u>
16	PP → RP	r	>330	>330	<u>110</u>	198	<u>23</u>	<14
17	PP → RP	r	>330	>330	<u>102</u>	>330	>330	<u>123</u>
18	PP → RP	r	>330	<u>65</u>	<14	>330	<u>75</u>	<14
19	PP → RP	l	>330	<u>164</u>	<u>21</u>	>330	<u>48</u>	<14
20	PP → RP	l	>330	>330	<u>99</u>	>330	>330	<u>86</u>
21	PP → RP	l	>330	>330	<u>87</u>	>330	<u>284</u>	<u>31</u>
22	PP → RP	l	>330	>330	<u>53</u>	>330	>330	<u>71</u>
23	PP → RP	l	>330	>330	<u>82</u>	>330	>330	<u>65</u>
24	PP → RP	l	>330	>330	<u>116</u>	>330	>330	<u>135</u>

Period of analysis: 16.8.2022 - 31.8.2022

16.8.-17.8.2022, 30.8.-31.8.2022

Prepared by: Mgr. Alena Holiková

REPORT OF ANALYSIS No. 80248/21/ROBCH

Client ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU		Sample number: 80248/21/ROBCH Sample description (according to declaration of Client) DEZINFECTANT UNIVERSAL "BIO-DEZ" Lot: - Data fabricatie: 01.10.2021 Data expirarii: 01.10.2024 Data prelevării: - Cantitate prelevata: 2 x 500 ml Responsabil prelevare: CRESTINOV ALEXANDR Ora receptiei probei: 15:30 Temperatura receptie proba: 15°C Sample condition with no objections Order of 11.10.2021 Sampling and delivery were carried out by client.	
Sample received:	11.10.2021		
Tests performed:	21.10.2021		
Tests completed:	13.12.2021		
Report dated:	13.12.2021		

Test	Method	Unit	Result
# * Fungicidal activity in medical area. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1).	EN 13624:2014	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/21/B0644 , issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory
Authorized by: Mariana Ilinca, Manager of Microbiological Laboratory
Approved by: Alina-Roxana Mihai, General Manager (Approved with qualified electronic signature)

Laboratory: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevării probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de incredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solidtati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Test method accredited # Test performed by external provider

o Non accredited methods



A) IDENTIFICATION OF THE SAMPLE	
Name of the product/Details about the product	DEZINFECTANT UNIVERSAL "BIO-DEZ" Expiration date: 01.10.2024. Manufacturer (supplier): Ecochim-Grup SRL. Storing conditions: Dry, without sun, 5-25 Celsius degree. Conditions of use: Hygienic handrub, surface disinfection, medical instruments disinfection, surgical handrub
Active compound/s and its concentration/s	Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6. Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2, Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2
Concentrations requested for the assay	Pure (80%).
B) TEST METHOD	
Performed in accredited contracted partner laboratory, Scope of Accreditation Nr. 648/LE1286 Report Registration No. D/21/B0644 Quantitative evaluation assay of yeasticidal activity under dirty conditions, in the medical area (phase 2, step 1), with product Desinfectant Universal "Bio-Dez", (UNE-EN 13624: 2014 Standard).	UNE-EN 13624:2014 Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of the fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1). AENOR.
Testing method	Procedure DESIN-1058-b // EN 13624:2014
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of order with test conditions	21.10.2021
Date of reception of the sample	25.10.2021
Aspect of the received product	Blue liquid in plastic package
D) METHOD OF ASSAY AND ITS VALIDATION (UNE-EN 13624: 2014 Standard)	
Method used	Dilution-neutralization
Neutralizer	Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soy lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and Saponin 30 g/L.
E) EXPERIMENTAL CONDITIONS	
Assay period	2021/11/08 to 2021/11/14.
Solvent of the product used in the assay	Sterile distilled water.
Product concentrations for the assay	Pure (80%), 50%, 0.1%
Aspect of the dilutions of the product	Pure (80%) and 50% blue liquid; 0.1% transparent.
Contact time	60 seconds
Assay temperature	+20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile distilled water)	Stable
Temperature of incubation	+30°C ± 1°C
Identification of the strain used	<i>Candida albicans</i> CECT-1394 (ATCC 10231)

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80248/21/ROBCH

Results of the assay

- Assay of validation See tables 1 and 2.
- Evaluation of yeasticidal activity See table 3.
- Number of replicates per assay organism 1.

Special remarks

- All controls and validation were between the basic limits.
- At least one concentration of the sample showed a log reduction lower than 4 log.
- At least one concentration of the sample showed a log reduction higher than 4 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.
- No precipitate formed during the test procedure (the test mixtures were homogeneous).

Conclusion

The product **Desinfectant Universal“Bio-Dez”**, batch not indicated, when is pure (80%), shows yeasticidal activity after 60 seconds at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), for the reference strain *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by the **UNE-EN 13624: 2014 Standard**.

Note: The results obtained correspond to the sample received in the laboratory.

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials, and reagents, following the Good Laboratory Practices (GLPs) as well and the final report contains the primary data obtained.

Reference

- **UNE-EN 13624 : 2014**. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of the fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1). AENOR.

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Enclosure no. 1 subcontracted tests

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80248/21/ROBCH
Results of the assay with *Candida albicans* (CECT 1394 = ATCC 10231).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 1.-Validation and controls.

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of neutralizer (B)			Validation of the method (C) Sample concentration: Pure (80%)		
V_{C1}	86	$X=90$	V_{C1}	72	$X=74$	V_{C1}	75	$X=73$	V_{C1}	66	$X=$
V_{C2}	94		V_{C2}	76		V_{C2}	71		V_{C2}	61	63.5
$30 \leq x \text{ of } N_{V0} \leq 160?$ Yes			$x \text{ of } A \text{ es } \geq 0,5 X \text{ de } N_{V0}?$ Yes			$x \text{ of } B \text{ es } \geq 0,5 X \text{ de } N_{V0}, \text{ or } 0.0005 N_{VB}?$ Yes			$x \text{ of } C \text{ es } \geq 0.5 X \text{ of } N_{V0}?$ Yes		
Suspension of validation (N_{VB})			$V_{C1}: 79 \quad V_{C2}: 77$			$X=78$ $30 \leq x \text{ de } N_{VB}/1000 \leq 160?$ Yes					

Table 2. -Suspension of the assay.

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 3.35 \times 10^7$
	10^{-5}	>330	>330	$\lg N = 7.53$ $N_0 = N/10$
	10^{-6}	32	35	$\lg N_0 = 6.53$ $6.17 \leq \lg N_0 \leq 6.70? \text{ Yes}$

Table 3.-Results of the activity assays with the sample.

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ or } X_{mw} \times 10)$	$\lg R$ ($\lg N_0 = 6.53$)	Time of contact (seconds)
Pure (80%)	Na^0	<14	<14	<2.15	>4.38	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>4.38	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.01	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = ponderated mean of X

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2); R (reduction): ($\lg R = \lg N_0 - \lg Na$).

Laboratory: Bucharest 041914, 8 Berceni Street.

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*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

REPORT OF ANALYSIS No. 80249/21/ROBCH

Client ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU		Sample number: 80249/21/ROBCH Sample description <i>(according to declaration of Client)</i> DEZINFECTANT UNIVERSAL "BIO-DEZ" Lot: - Data fabricatie: 01.10.2021 Data expirarii: 01.10.2024 Data prelevării: - Cantitate prelevata: 1 x 500 ml Responsabil prelevare: CRESTINOV ALEXANDR Ora receptiei probei: 15:30 Temperatura receptie proba: 15°C Sample condition with no objections Order of 11.10.2021 Sampling and delivery were carried out by client.	
Sample received:	11.10.2021		
Tests performed:	21.10.2021		
Tests completed:	13.12.2021		
Report dated:	13.12.2021		

Test	Method	Unit	Result
# * Quantitative suspension test for the evaluation of bactericidal activity in medical area	EN 13727:2012+A2:2015	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/21/B0645, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory
Authorized by: Mariana Ilinca, Manager of Microbiological Laboratory
Approved by: Alina-Roxana Mihai, General Manager *(Approved with qualified electronic signature)*

Laboratory: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevării probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de incredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solidtati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Test method accredited # Test performed by external provider

o Non accredited methods



ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

A) IDENTIFICATION OF THE SAMPLE	
Name of the product/Details about the product	DEZINFECTANT UNIVERSAL "BIO-DEZ" Expiration date: 01.10.2024. Manufacturer (supplier): Ecochim-Grup SRL. Storing conditions: Dry, without sun, 5-25 Celsius degree. Conditions of use: Hygienic handrub, surface disinfection, medical instruments disinfection, surgical handrub
Active compound/s and its concentration/s	Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6. Benzalkonium chloride 0.024- 0.029%, CAS 68424-85-1 and CE 270-325-2, Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2
Concentrations requested for the assay	Pure (80%).
B) TEST METHOD	
Performed in accredited contracted partner laboratory, Scope of Accreditation Nr. 648/LE1286 Report Registration No. D/21/B0645 Quantitative evaluation assay of the bactericidal activity under dirty conditions, in the medical area (phase 2, step 1) with product Desinfectant Universal "Bio-Dez", (UNE-EN 13727: 2012 + A2: 2015 Standard).	UNE-EN 13727: 2012 + A2: 2015. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in Medicine. Test method and requirements (phase 2, step 1). AENOR.
Testing method	DESIN-1031-b //EN 13727: 2012 + A2: 2015
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of order with test conditions	21.10.2021
Date of reception of the sample	25.10.2021
Aspect of the received product	Blue liquid in plastic package
D) METHOD OF ASSAY AND ITS VALIDATION (UNE-EN 13727: 2012+A2: 2015 Standard.)	
Method used	Dilution-neutralization
Neutralizer	Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.
E) EXPERIMENTAL CONDITIONS	
Assay period	2021/11/10 to 2021/11/14.
Solvent of the product used in the assay	Sterile distilled water.
Product concentrations for the assay	Pure (80%), 50%, 0.1%
Aspect of the dilutions of the product	Pure (80%) and 50% blue liquid; 0.1% transparent.
Contact time	60 seconds
Assay temperature	+20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile distilled water)	Stable
Temperature of incubation	+36°C ± 1°C
Identification of the strain used	- <i>Pseudomonas aeruginosa</i> (CECT 116 = ATCC 15442). - <i>Staphylococcus aureus</i> (CECT 239 = ATCC 6538). - <i>Enterococcus hirae</i> (CECT 4081 = ATCC 10541). - <i>Escherichia coli</i> K12 (CECT 433 = NCTC 10538).

Laboratory: Bucharest 041914, 8 Berceni Street.

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*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

Results of the assay

- Assay of validation See tables 1, 2, 4, 5, 7, 8, 10 and 11.
- Evaluation of bactericidal activity See tables 3, 6, 9 and 12.
- Number of replicates per assay organism .. 1.

Special remarks

- All controls and validation were between the basic limits.
- At least one concentration of the sample showed a log reduction lower than 5 log.
- At least one concentration of the sample showed a log reduction higher than 5 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.
- No precipitate formed during the test procedure (the test mixtures were homogeneous).

Conclusion

The product Desinfectant Universal "Bio-Dez", batch not indicated, when is pure (80%), shows bactericidal activity after 60 seconds at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), for the reference strains *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442), *Staphylococcus aureus* (CECT 239 = ATCC 6538), *Enterococcus hirae* (CECT 4081 = ATCC 10541) and *Escherichia coli* K12 (CECT 433 = NCTC 10538), when tested according to UNE-EN 13727: 2012 + A2: 2015 Standard.

Note: The results obtained correspond to the sample received in the laboratory.

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials, and reagents, following the Good Laboratory Practices (GLPs) as well and the final report contains the primary data obtained.

Reference

- UNE-EN 13727: 2012 + A2: 2015. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in Medicine. Test method and requirements (phase 2, step 1). AENOR.

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Enclosure no. 1 subcontracted tests

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

Results of the assay (Bactericidal suspension) with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442).

Seeding: Pour plate; No. of plates: 1/mL.

Table 1.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of neutralizer (B)			Validation of the method (C) Sample concentration: Pure (80%)		
V_{C1}	61	$X=$	V_{C1}	53	$X=$ 54	V_{C1}	46	$X=$ 48	V_{C1}	42	$X=$
V_{C2}	56	58.5	V_{C2}	55		V_{C2}	50		V_{C2}	37	39.5
$30 \leq x \text{ of } N_{V0} \leq 160?$			$x \text{ of } A \text{ es } \geq 0,5 X \text{ de } N_{V0}?$			$x \text{ of } B \text{ es } \geq 0,5 X \text{ de } N_{V0}, \text{ or } 0.0005 N_{VB}?$			$x \text{ of } C \text{ es } \geq 0,5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			V_{C1} : 57 V_{C2} : 63			$X = 60$ $30 \leq x \text{ de } N_{VB}/1000 \leq 160?$ Yes					

Table 2.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 2.25 \times 10^8$, $\lg N = 8.35$ $N_0 = N/10$; $\lg N_0 = 7.35$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	217	234	
	10^{-7}	21	22	

Table 3.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.35$)	Time of contact (seconds)
Pure (80%)	Na^0	<14	<14	<2.15	>5.20	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.20	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.83	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

Laboratory: Bucharest 041914, 8 Berceni Street.

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Enclosure no. 1 subcontracted tests

Page 3 of 6

PGL 09 F 04 Ed. 1 Rev. 0

Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

Results of the assay (Bactericidal suspension) with *Staphylococcus aureus* (CECT 239 = ATCC 6538).

Seeding: Pour plate; No. of plates: 1/mL.

Table 4.-Validation and controls

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Control of neutralizer (B)			Validation of the method (C) Sample concentration: Pure (80%)		
V_{c1}	77	$X=74$	V_{c1}	68	$X=68.5$	V_{c1}	75	$X=78.5$	V_{c1}	70	$X=66$
V_{c2}	71		V_{c2}	69		V_{c2}	82		V_{c2}	62	
$30 \leq x \text{ of } N_{v0} \leq 160?$ Yes			$x \text{ of } A \text{ es } \geq 0,5 X \text{ de } N_{v0}?$ Yes			$x \text{ of } B \text{ es } \geq 0,5 X \text{ de } N_{v0}, \text{ or } 0.0005 N_{vB}?$ Yes			$x \text{ of } C \text{ es } \geq 0,5 X \text{ of } N_{v0}?$ Yes		
Suspension of validation (N_{vB})			$V_{c1}: 79 \quad V_{c2}: 86$			$X=82.5$ $30 \leq x \text{ de } N_{vB}/1000 \leq 160?$ Yes					

Table 5.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{c1}	V_{c2}	$X_{wm} = 3.40 \times 10^8$, $\lg N = 8.53$ $N_0 = N/10$; $\lg N_0 = 7.53$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	>330	>330	
	10^{-7}	33	35	

Table 6.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.53$)	Time of contact (seconds)
Pure (80%)	Na^0	<14	<14	<2.15	>5.38	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.38	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<3.01	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{c1} and V_{c2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

Laboratory: Bucharest 041914, 8 Berceni Street.

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*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

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Enclosure no. 1 subcontracted tests

Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

Results of the assay (Bactericidal suspension) with *Enterococcus hirae* (CECT 4081 = ATCC 10541).

Seeding: Pour plate; No. of plates: 1/mL.

Table 7.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of neutralizer (B)			Validation of the method (C) Sample concentration: Pure (80%)		
V_{C1}	41	$X=43$	V_{C1}	44	$X=$	V_{C1}	37	$X=$	V_{C1}	35	$X=36$
V_{C2}	45		V_{C2}	43	41.5	V_{C2}	40	38.5	V_{C2}	37	
$30 \leq x \text{ of } N_{V0} \leq 160?$ Yes			$x \text{ of } A \text{ es } \geq 0,5 X \text{ de } N_{V0}?$ Yes			$x \text{ of } B \text{ es } \geq 0,5 X \text{ de } N_{V0}, \text{ or } 0,0005 N_{VB}?$ Yes			$x \text{ of } C \text{ es } \geq 0,5 X \text{ of } N_{V0}?$ Yes		
Suspension of validation (N_{VB})			V_{C1} : 39 V_{C2} : 42			$X=40,5$ $30 \leq x \text{ de } N_{VB}/1000 \leq 160?$ Yes					

Table 8.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.61 \times 10^8$, $\lg N = 8.20$ $N_0 = N/10$; $\lg N_0 = 7.20$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	167	154	
	10^{-7}	17	16	

Table 9.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.20$)	Time of contact (seconds)
Pure (80%)	Na^0	<14	<14	<2.15	>5.05	60
	Na^{-1}	<14	<14			
50%	Na^0	15	14	2.16	5.04	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.68	60
	Na^{-1}	>330	>330			

Explanations:

V_C = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Enclosure no. 1 subcontracted tests

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

Results of the assay (Bactericidal suspension) with *Escherichia coli* K12 (CECT 433 = NCTC 10538).

Seeding: Pour plate; No. of plates: 1/mL.

Table 10.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of neutralizer (B)			Validation of the method (C) Sample concentration: Pure (80%)		
V_{C1}	58	$X=60$	V_{C1}	44	$X=45$	V_{C1}	51	$X=50$	V_{C1}	43	$X=41$
V_{C2}	62		V_{C2}	46		V_{C2}	49		V_{C2}	39	
$30 \leq x \text{ of } N_{V0} \leq 160?$			x of A es $\geq 0,5 X$ de $N_{V0}?$			x of B es $\geq 0,5 X$ de N_{V0} , or $0.0005 N_{VB}?$			x of C es $\geq 0.5 X$ of $N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			V_{C1} : 54 V_{C2} : 56			$X=55$ $30 \leq x \text{ de } N_{VB}/1000 \leq 160?$ Yes					

Table 11.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 2.49 \times 10^8$, $\lg N = 8.40$ $N_0 = N/10$; $\lg N_0 = 7.40$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	241	259	
	10^{-7}	22	25	

Table 12.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.40$)	Time of contact (seconds)
Pure (80%)	Na^0	<14	<14	<2.15	>5.25	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.25	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.88	60
	Na^{-1}	>330	>330			

Explanations:

V_C = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Enclosure no. 1 subcontracted tests

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

REPORT OF ANALYSIS No. 17898/21/ROBCH

Client ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU		Sample number: 17898/21/ROBCH Sample description <i>(according to declaration of Client)</i> DEZINFECTANT UNIVERSAL "BIO-DEZ" Sample quantity: 1 pcs x 1 L Production date: 26.01.2021 Expiration date: 26.01.2024 Sampling date: 22.02.2021 Sample temperature: 15°C Reception hour: 15:00 Responsible for sampling: Crestinov Alexandr
Sample received:	15.03.2021	Sample condition with no objections Order of 15.03.2021 Sampling and delivery were carried out by client.
Tests performed:	21.04.2021	
Tests completed:	16.06.2021	
Report dated:	16.06.2021	

Test	Method	Unit	Result
# * Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1)	EN 14348: 2005	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/21/B0152, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory

Authorized by: Mariana Ilinca, Manager of Microbiological Laboratory

Approved by: Alina-Roxana Mihai, General Manager *(Approved with qualified electronic signature)*

Laboratory: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevarii probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de incredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solidtati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Test method accredited # Test performed by external provider

ø Non accredited methods



A) IDENTIFICATION OF THE SAMPLE	
Name of the product/Details about the product	DEZINFECTANT UNIVERSAL "BIO-DEZ" Expiration date: 26.01.2024 Manufacturer (supplier): ECOCHIM-GRUP Storing conditions: Dry, without sun, 5-25 Celsius degree. Conditions of use: Handrub
Active(S) substance (S) and its concentration(s)	Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6; Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2; Methylthionium chloride 0.00024%, CAS 61-73-4 and 200
Concentrations requested for the assay	3%/ on May 5 the client requested to perform the test at 80% concentration (Pure).
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report D/21/B0152 Mycobactericidal and tuberculocidal activity of chemical disinfectants in the medical area including instrument disinfectants under clean conditions with the product DEZINFECTANT UNIVERSAL "BIO-DEZ" with deviations from the standard (UNE-EN 14348: 2005 Standard)	UNE-EN 14348: 2005. Chemical disinfectants and antiseptics . Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1). AFNOR
C) METHOD OF ASSAY AND ITS VALIDATION (UNE-EN 14348: 2005 Standard)	
Testing method	DESIN-1052-b // EN 14348: 2005
Method used	Dilution-neutralization
Neutralizer	Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponim 30 g/L.
D) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	24.03.2021
Date of reception of order with test conditions	14.04.2021: 3% concentration 05.05.2021: 80% concentration
Aspect of the received product	Blue liquid in plastic package.
E) EXPERIMENTAL CONDITIONS	
Assay period	2021/04/12 to 2021/05/24 (including prior preparation of the strains)
Solvent of the product used in the assay	Sterile hard water
Product concentrations for the assay	Pure (80%), 3% and 0.1%
Aspect of the dilutions of the product	Pure (80%) Blue liquid; 3% and 0.1% transparent
Contact time	60 seconds
Assay temperature	20°C ± 1°C
Interfering substance	Bovine albumin 0.3 g/L
Stability of the mixture (interfering substance and product diluted in sterile hard water)	stable
Temperature of incubation	36°C ± 1°C
Identification of the origin of viral stains and number of passes	<i>Mycobacterium avium</i> (ATCC 15769) <i>Mycobacterium terrae</i> (CECT 3028 = ATCC 15755)

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 09.06.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

Results of the assay

- Control and validation assays..... See tables 1, 2, 4 and 5
- Evaluation of mycobactericidal activity... See tables 3 and 6.
- Number of replicates for each assay microorganism..... 1.

Special remarks

- All controls and validation were between the basic limits.
- One concentration of the sample at least showed a log reduction less than 4 log.
- One concentration of the sample at least showed a log reduction higher than 4 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.
- When the client requested to perform the test at 80% concentration, the test had been started, using hard water.

Conclusion

The product **DEZINFECTANT UNIVERSAL „BIO-DEZ”**, batch not indicated, when tested pure (80%), shows **mycobactericidal activity** after 60 seconds at 20°C under clean conditions (bovine albumin 0.3 g/L), against *Mycobacterium avium* (ATCC 15769) and *Mycobacterium terrae* (CECT 3028 = ATCC 15755), when tested as required by **UNE-EN 14348: 2005 Standard** with deviations from the standard since the dilutions of the product, ready to use, have been prepared in sterile hard water instead of in sterile distilled water. The client informed us that the product was ready to use once the test have been started.

Note: The results obtained correspond to the sample received in the laboratory.

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials and reagents, following as well the Good Laboratory Practices (GLPs) and the final report contains the primary data obtained.

Reference:

- **UNE-EN 14348: 2005.** Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1). AENOR.

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Enclosure no. 1 subcontracted tests

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 09.06.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17898/21/ROBCH
Table 1.-Assay with *Mycobacterium avium* (ATCC 15769): Validation and controls.

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Neutralizer (B)			Validation of the method (C) with sample concentration: Pure (80%)		
V_{c1}	135	$X=$	V_{c1}	125	$X=122$	V_{c1}	121	$X=124$	V_{c1}	130	$X=$
V_{c2}	124	129.5	V_{c2}	119		V_{c2}	127		V_{c2}	119	
$30 \leq x \text{ of } N_{v0} \leq 160?$ Yes			$x \text{ of } A \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ Yes			$x \text{ of } B \text{ is } \geq 0.5 \times x \text{ of } N_{v0}?$ Yes			$x \text{ of } C \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ Yes		

Table 2.- Assay with *Mycobacterium avium* (ATCC 15769): Suspension of the assay.

Suspension of the assay (N_y N_0)	N	V_{c1}	V_{c2}	$X_{wm} = 4.85 \times 10^9 = \lg = 9.69$ $N_0 = N/10 = \lg = 8.69$ $8.17 \leq N_0 \leq 8.70?$ Yes
	10^{-7}	>660	>660	
	10^{-8}	51	46	

Table 3.- Assay with *Mycobacterium avium* (ATCC 15769).

Concentrations of the sample (%)	Dilutions	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R (\lg N_0 = 8.69)$	Time of contact (seconds)
Pure (80%)	10^0	<14	<14	<2.15	>6.54	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
3%	10^0	>660	>660	>6.82	<1.87	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			
0.1%	10^0	>660	>660	>6.82	<1.87	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			

Observations:

N 10^{-7} : >330 + >330; >330 + >330;
 10^{-8} : 28 + 23; 27 + 19;

N_{v0} : 74 + 61; 59 + 65;

A : 68 + 57; 60 + 59;

B : 63 + 58; 71 + 57;

C : 72 + 58; 55 + 64;

Na Pure (80%) 10^0 : 0 + 0; 0 + 0;

3% 10^{-3} : >330 + >330; >330 + >330;

0.1% 10^{-3} : >330 + >330; >330 + >330;

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 09.06.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

Table 4.- Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755): Validation and controls.

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Neutralizer (B)			Validation of the method (C) with sample concentration: Pure (80%)		
V_{C1}	53	X= 55	V_{C1}	54	X= 52	V_{C1}	50	X= 49	V_{C1}	49	X= 47
V_{C2}	57		V_{C2}	50		V_{C2}	48		V_{C2}	45	
30 ≤ x of N_{v0} ≤ 160? Yes			x of A is ≥ 0.5 x X of N_{v0} ? Yes			x of B is ≥ 0.5 x of N_{v0} ? Yes			x of C is ≥ 0.5 X of N_{v0} ? Yes		

Table 5.- Assay with *Mycobacterium terrae* (CECT 3028 = ATCC-15755): Suspension of the assay.

Suspension of the assay (N_y) N_0	N	V_{c1}	V_{c2}	$X_{nm} = 2.19 \times 10^9 = \lg = 9.34$ $N_0 = N/10 = \lg = 8.34$ $8.17 \leq N_0 \leq 8.70?$ Yes
	10^{-7}	227	211	
	10^{-8}	21	22	

Table 6.- Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755).

Concentrations of the sample (%)	Dilutions	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 8.34$)	Time of contact (seconds)
Pure (80%)	10^0	<14	<14	<2.15	>6.19	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
3%	10^0	>660	>660	>6.82	<1.52	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			
0.1%	10^0	>660	>660	>6.82	<1.52	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			

Observations:

N 10^{-7} : 103 + 124; 99 + 112;
 10^{-8} : 13 + 8; 10 + 12;

Na Pure (80%) 10^0 : 0 + 0; 0 + 0;
 3% 10^{-3} : >330 + >330; >330 + >330;
 0.1% 10^{-3} : >330 + >330; >330 + >330;

N_{v0} : 29 + 24; 32 + 25;

A : 31 + 23; 26 + 24;

B : 19 + 31; 27 + 21;

C : 33 + 16; 21 + 24;

Explanations:

V_c : Counts per mL

X_{wm} : ponderated mean of X

X : Values of V_{c1} and V_{c2} (1. + 2. duplicates); R : reduction ($\lg R = \lg N_0 - \lg Na$)

R : reduction ($\lg R = \lg N_0 - \lg Na$)

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Enclosure no. 1 subcontracted tests

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 09.06.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

Laboratory: Bucharest 041914, 8 Berceni Street.

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Enclosure no. 1 subcontracted tests

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 09.06.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

RAPORT DE INCERCARE NR. 17899/21/ROBCH/Z1

Inlocuieste Raportul de Incercare Nr. 17899/21/ROBCH din 26.04.2021

Client ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU		Numă rul esantionului: Sample number Descriere obiect de incercat (conform cu declaratia Clientului) DEZINFECTANT UNIVERSAL "BIO-DEZ" Sample quantity: 1 pcs x 1 L Production date: 26.01.2021 Expiration date: 26.01.2024 Sampling date: 22.02.2021 Sample temperature: 15°C Reception hour: 15:00 Responsible for sampling: Crestinov Alexandr Sample condition with no objections
Data primirii obiectului de incercat:	15.03.2021	Comanda din 15.03.2021 Probele au fost prelevate si livrate de catre Client.
Data finalizarii incercarii:	26.04.2021	
Data eliberarii raportului:	14.09.2021	

Parametrii de testare	Metoda de testare	Unitate de masura	Rezultat
# * Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity in the medical area	UNE-EN 14476:2014 + A2:2019	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/21/V0204, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborat de: Mariana Ilinca, Sef Laborator Microbiologie
Autorizat de: Mariana Ilinca, Sef Laborator Microbiologie
Aprobat de catre: Alina-Roxana Mihai, General Manager (Aprobat cu semnatura electronica)

Laborator: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevarii probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de incredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solicitati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Metoda de testare acreditata # Test efectuat de catre subcontractor

o Incercari neacreditate

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17899/21/ROBCH/Z1
A) IDENTIFICATION OF THE SAMPLE

Name of the product/Details about the product	DEZINFECTANT UNIVERSAL "BIO-DEZ" Sample quantity: 1 pcs x 1 L Production date: 26.01.2021 Expiration date: 26.01.2024 Manufacturer(supplier): ECOCHIM-GRUP Dry, without sun, 5-25°C
Active(s) Substance(s) and its concentration(s)	Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6; Benzalkonium chloride 0,024-0,029%, CAS 68424-85-1 and CE 270-325-2; Methylthioninium chloride 0,00024%, CAS 61-73-4 and 200.
Concentration ordered for the assay	3%

B) TEST METHOD

Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report D/21/V0204- Modified report Virucidal test with the sample DEZINFECTANT UNIVERSAL "BIO-DEZ" against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus (NF EN 14476:2013+A2:2019 Standard)	NF EN 14476:2013+A2:2019 Standard. Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (Phase 2/Step1).AFNOR
Testing method	Procedure DESIN-1078 (NF EN 14476:2013+ A2:2019 Standard)

C) INFORMATION ABOUT SAMPLE RECEPTION

Date of reception of the sample	22.03.2021
Date of reception of order with test conditions	22.03.2021
Aspect of the received product	Blue transparent liquid in a plastic container

D) EXPERIMENTAL CONDITIONS

Assay period	From 22.03.2021 to 01.04.2021
Assay temperature	37°C ± 1°C
Titration method	TCID50 (Tissue Culture Infective Dose 50%)
Product concentrations for the assay	80%, 3% and 0.03%
Contact time	60 seconds
Contact temperature	20°C ± 1°C
Procedure to stop product cytotoxicity	Molecular sieving (< 4 columns)
Procedure to stop product activity	Cooling with ice
Solvent of the product used in the assay	Hard water
Aspect of the dilutions of the product	Transparent
Stability of the mixture (interfering substance and product diluted in sterile hard water/distilled water)	Stable
Interfering substance	Clean conditions in the presence of bovine serum albumin 0.3 g/L.
Identification of the origin of viral stains and number of passes	Poliovirus type 1 aliquot: 2021/01/07 passage 2; Adenovirus type 5 aliquot: 2021/01/14 passage 2; Murine Norovirus aliquot: 2021/02/11 passage 2;
Cell lines (name, origin, number of passes)	Vero ref: FTVE, working aliquot 12 passages 13 and 17; Raw 264.7, Public Health England, working aliquot 12, passages 12, 16 and 18;

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 13.09.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17899/21/ROBCH/Z1

Note: Modified report due to the client requests to add the 80% concentration results in the conclusions section.

Validation of assay results

Poliovirus type 1 (ATCC VR-192)

Titre of the viral suspension for the virus control (at the requested test time):

• Clean conditionslog 10^{-7.24}
Cytotoxicity level (80%)log 10^{-0.50}

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):

• Clean conditionslog 10^{-6.74}

Adenovirus type 5 (ATCC VR-5)

Titre of the viral suspension for the virus control (at the requested test time):

• Clean conditionslog 10^{-6.33}
Cytotoxicity level (80%)log 10^{-0.50}

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):

• Clean conditionslog 10^{-5.83}

Murine Norovirus (strain S99 Berlin)

Titre of the viral suspension for the virus control (at the requested test time):

• Clean conditionslog 10^{-6.16}
Cytotoxicity level (80%)log 10^{-0.50}

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):

• Clean conditionslog 10^{-5.66}

Reference test (formaldehyde 1.4%)

Cytotoxicity level of formaldehyde 0.7% log10^{-0.50}

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Poliovirus type 1log10^{-3.32}

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Adenovirus type 5log10^{-1.41}

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Murine Noroviruslog10^{-2.66}

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Confidence interval

Titre of virus with 95% confidence interval with Poliovirus type 1 (at the requested test time):

○ Clean conditions $\log 10^{-7.24 \pm 0.37}$

Titre of virus with 95% confidence interval with Adenovirus type 5 (at the requested test time):

○ Clean conditions $\log 10^{-6.33 \pm 0.40}$

Titre of virus with 95% confidence interval with Murine Norovirus (at the requested test time):

○ Clean conditions $\log 10^{-6.16 \pm 0.34}$

Reduction with the confidence interval of 95 % See table 1.

Sensitivity of cells to virus

- Viral quantification of Poliovirus type 1 with cells not treated by the test solution with the test sample $\log 10^{-7.15}$
- Viral quantification of Poliovirus type 1 with cells treated by the test solution with the test sample $\log 10^{-6.58}$
- Viral quantification of Adenovirus type 5 with cells not treated by the test solution with the test sample $\log 10^{-6.07}$
- Viral quantification of Adenovirus type 5 with cells treated by the test solution with the test sample $\log 10^{-5.66}$
- Viral quantification of Murine Norovirus with cells not treated by the test solution with the test sample $\log 10^{-6.16}$
- Viral quantification of Murine Norovirus with cells treated by the test solution with the test sample $\log 10^{-5.66}$

Note: only can be used to determine the infectivity of cells, those dilutions which: a) show a low degree of cellular destruction (< 25% of cell monolayer) and b) produce a reduction of the titre of the virus < 1 $\log_{10}$.

Control of the effectivity of the disinfectant detection activity

- Viral quantification of Poliovirus type 1 after 30 minutes on bath ice without exposing the virus to the test sample $\log 10^{-7.07}$
- Viral quantification of Poliovirus type 1 exposing the virus to the test sample and incubated 30 minutes on ice bath $\log 10^{-6.66}$
- Viral quantification of Adenovirus type 5 after 30 minutes on bath ice without exposing the virus to the test sample $\log 10^{-6.16}$
- Viral quantification of Adenovirus type 5 exposing the virus to the test sample and incubated 30 minutes on ice bath $\log 10^{-5.74}$

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17899/21/ROBCH/Z1

- Viral quantification of Murine Norovirus after 30 minutes on bath ice without exposing the virus to the test samplelog10^{-6.32}
- Viral quantification of Murine Norovirus exposing the virus to "the test sample and incubated 30 minutes on ice bathlog10^{-5.99}

Note: The difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension should be ≤ 0.5

Special remarks

- The sample is tested at 80%; 3% and 0.03%. The highest concentration that can be tested in the test is 80%, because of the mixtures made during the test.
- All controls and validation were between the basic limits.
- One concentration at least showed a log reduction less than 4 log.
- One concentration at least showed a log reduction equal or higher than 4 log.

Assay results
Description of the results under the requested test conditions:

Virus of assay	Test concentrations, reduction obtained with the confidence interval of 95 % and virucidal activity		
	80%	3%	0.03%
Poliovirus type 1	5.33 ± 0.49 TCID ₅₀ Shows	0.83 ± 0.54 TCID ₅₀ Does not show	0.17 ± 0.55 TCID ₅₀ Does not show
Adenovirus type 5	≥ 5.83 ± 0.40 TCID ₅₀ Shows	1.51 ± 0.52 TCID ₅₀ Does not show	0.17 ± 0.56 TCID ₅₀ Does not show
Murine Norovirus	≥ 5.66 ± 0.34 TCID ₅₀ Shows	2.17 ± 0.48 TCID ₅₀ Does not show	0.09 ± 0.53 TCID ₅₀ Does not show

Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.

TCID₅₀: Tissue Culture Infectious Dose 50%.

Tables of results and graphics

See tables 1 to 6 and figure 1 to 3.

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Conclusion

The disinfectant sample "**DEZINFECTANT UNIVERSAL, BIO-DEZ**", batch not indicated, under clean conditions (bovine serum albumin 0.3 g/L), at **3%** concentration, requested by the client, and during 60 seconds of contact time and 20°C of temperature, **does not show** virucidal activity against the three mandatory viruses (Poliovirus type 1, Adenovirus type 5 and Murine Norovirus) when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 Standard. However, the disinfectant sample "**DEZINFECTANT UNIVERSAL, BIO-DEZ**", batch not indicated, under clean conditions (bovine serum albumin 0.3 g/L), at **80%** concentration and during 60 seconds of contact time and 20°C of temperature, **shows** virucidal activity against the three mandatory viruses (Poliovirus type 1, Adenovirus type 5 and Murine Norovirus) when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 Standard.

Therefore, the disinfectant tested, **does not show general virucidal activity**, diluted at **3%** and **it shows general virucidal activity**, diluted at **80%** when the activity is evaluated according to the NF EN 14476: 2013 + A2: 2019 Standard.

Note 1: The results obtained correspond to the sample received in this laboratory.

Note 2: The information that depend on the information received from the client and are not facilitated by the same one, shown as "not indicated".

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials and reagents, following as well the Good Laboratory Practices (GLPs) and the final report contains the primary data obtained.

Reference:

- **NF EN 14476: 2013 + A2: 2019 Standard.** Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (Phase 2/Step 1). AFNOR.

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17899/21/ROBCH/Z1
Table 1. Results of activity of the sample test sample with Poliovirus type 1 (ATCC VR-192) under test conditions requested by the client.

Assay	Concentration*	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after.....				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 min	
Test sample	80%	0.3 g/L BSA	0.5	-	1.91	-	-	5.33 ± 0.49
	3%		0.5	-	6.41	-	-	0.83 ± 0.54
	0.03%		0.5	-	7.07	-	-	0.17 ± 0.55
Virus control	NA	0.3 g/L BSA	NA	7.32	7.24	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.5	NR	NR	5.16	3.32	NA
Virus control Formaldehyde	0.7% (w:v)	NA	0.5	7.07	NR	NR	6.99	NA
Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells)log10 ^{-0.57}								
Control of the effectiveness of the disinfectant detection activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension).....log10 ^{-0.41}								
NA: not applicable; NR: not realized Times recommended by Standard for surfaces: maximum 5 or 60 minutes. Times recommended by Standard for instruments: maximum 60 minutes. Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds. PBS: phosphate buffered saline; BSA: bovine serum albumin. Virucidal activity exists when the titre of virus shows a reduction ≥4 log. *: see Special remarks to understand the values of these concentrations.								

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17899/21/ROBCH/Z1
Table 2. Results of the activity of the test sample, with Poliovirus type 1 (ATCC VR-192)

(Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concentration *	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}							
				1	2	3	4	5	6	7	8
Test sample	80%	0.3 g/L BSA	60 sec	4444	2000	0000	0000	0000	0000	0000	NR
				4444	3000	0001	0000	0000	0000	0000	
				4444	0320	0000	0000	0000	0000	0000	
	3%		60 sec	4444	4444	4444	4444	4444	0230	1000	NR
				4444	4444	4444	4444	4444	3424	0201	
				4444	4444	4444	4444	4444	0403	0000	
	0.03%		60 sec	4444	4444	4444	4444	4444	3042	0201	0000
				4444	4444	4444	4444	4444	3343	1302	0000
				4444	4444	4444	4444	4444	2444	0020	1100
Cytotoxicity	80%	0.3 g/L BSA	NA	0000	0000	0000	0000	0000	0000	0000	NR
				0000	0000	0000	0000	0000	0000		
				0000	0000	0000	0000	0000	0000		
Virus control	NA	0.3 g/L BSA	0	4444	4444	4444	4444	4444	4444	3023	0000
				4444	4444	4444	4444	4444	4444	4040	0102
				4444	4444	4444	4444	4444	4444	3320	0000
			60 sec	4444	4444	4444	4444	4444	4444	3000	0001
				4444	4444	4444	4444	4444	4444	3402	0020
				4444	4444	4444	4444	4444	4444	3023	0000
Formaldehyde	0.7% (w:v)	NA	30 min	4444	4444	4444	4444	2300	0002	0000	NR
				4444	4444	4444	4444	0302	0010	0000	
				4444	4444	4444	4444	2000	0100	0000	
			60 min	4444	4444	0320	0001	0000	0000	0000	NR
				4444	4444	2301	0010	0000	0000	0000	
				4444	4444	0332	0000	0000	0000	0000	
Control of formaldehyde cytotoxicity	0.7% (w:v)	0.3 g/L BSA	NA	0000	0000	0000	0000	0000	0000	0000	NR
				0000	0000	0000	0000	0000	0000		
				0000	0000	0000	0000	0000	0000		
Virus control formaldehyde	0.7% (w:v)	NA	0	4444	4444	4444	4444	4444	4444	0300	0001
				4444	4444	4444	4444	4444	4444	0204	0010
				4444	4444	4444	4444	4444	4444	2030	0000
			60 min	4444	4444	4444	4444	4444	3240	2301	0000
				4444	4444	4444	4444	4444	2444	0100	1000
				4444	4444	4444	4444	4444	3403	3202	0000
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0C0C	0000
				CCCC	CCCC	CCCC	CCCC	CCCC	0CCC	CC0C	0000
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0CCC	0000
			Cells treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0C00	0000
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	00C0	0000
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	00C0	0000
Effectiveness control of the disinfectant detection activity	NA	0.3 g/L BSA	Without sample	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	000C	0000
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CC0C	00C0
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0000	C000
			With sample	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0C00	0000
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0C0C	0000
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	C000	0000

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.

C = cytopathic effect with presence of virus (in this case and according to Standard, does not take into account the degree of cytopathic effect only, the presence or absence of the same).

0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline.

sec: seconds; min: minutes; *: see Special remarks to understand the values of these concentrations.

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Aprobato de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17899/21/ROBCH/Z1
Table 3. Results of activity of the test sample with Adenovirus type 5 (ATCC VR-5), under test conditions requested by the client.

Assay	Concentration*	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after.....				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 min	
Test sample	80%	0.3 g/L BSA	0.5	-	0.50	-	-	$\geq 5.83 \pm 0.40$
	3%		0.5	-	4.82	-	-	1.51 ± 0.52
	0.03%		0.5	-	6.16	-	-	0.17 ± 0.56
Virus control	NA	0.3 g/L BSA	NA	6.41	6.33	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.5	NR	NR	1.99	1.41	NA
Virus control Formaldehyde	0.7% (w:v)	NA	0.5	6.08	NR	NR	5.98	NA
Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells)log10 ^{-0.41}								
Control of the effectiveness of the disinfectant detection activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension).....log10 ^{-0.42}								
NA: not applicable; NR: not realized Times recommended by Standard for surfaces: maximum 5 or 60 minutes Times recommended by Standard for instruments: maximum 60 minutes Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds. PBS: phosphate buffered saline; BSA: bovine serum albumin. Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log. *: see Special remarks to understand the values of these concentrations.								

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17899/21/ROBCH/Z1
Table 4. Results of the activity of the test sample, with Adenovirus type 5 (ATCC VR-5)

(Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concentration *	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}							
				1	2	3	4	5	6	7	8
Test sample	80%	0.3 g/L BSA	60 sec	0000	0000	0000	0000	0000	0000	0000	NR
				0000	0000	0000	0000	0000	0000	0000	
	0000			0000	0000	0000	0000	0000	0000		
	3%		60 sec	4444	4444	4444	3342	0200	0000	0000	NR
				4444	4444	4444	0324	1202	0000	0000	
	4444			4444	4444	4344	0002	0000	0000		
0.03%	60 sec	4444	4444	4444	4444	4444	0200	0001	NR		
		4444	4444	4444	4444	4444	0330	0002			
4444		4444	4444	4444	4444	2020	0100				
Cytotoxicity	80%	0.3 g/L BSA	NA	0000	0000	0000	0000	0000	0000	0000	NR
				0000	0000	0000	0000	0000	0000	0000	
				0000	0000	0000	0000	0000	0000	0000	
Virus control	NA	0.3 g/L BSA	0	4444	4444	4444	4444	4444	3044	0001	NR
				4444	4444	4444	4444	4444	3023	0000	
				4444	4444	4444	4444	4444	4220	2000	
			60 sec	4444	4444	4444	4444	4444	0200	1000	NR
				4444	4444	4444	4444	4444	3304	0020	
				4444	4444	4444	4444	4444	0332	1000	
Formaldehyde	0.7% (w:v)	NA	30 min	4344	0200	0000	0000	0000	0000	0000	NR
				2324	1020	0000	0000	0000	0000	0000	
				4233	0002	1100	0000	0000	0000	0000	
			60 min	3002	0000	0000	0000	0000	0000	0000	NR
				3304	1000	0000	0000	0000	0000	0000	
				3422	0200	0000	0000	0000	0000	0000	
Control of formaldehyde cytotoxicity	0.7% (w:v)	0.3 g/L BSA	NA	0000	0000	0000	0000	0000	0000	0000	NR
				0000	0000	0000	0000	0000	0000	0000	
				0000	0000	0000	0000	0000	0000	0000	
Virus control formaldehyde	0.7% (w:v)	NA	0	4444	4444	4444	4444	3404	0201	0010	NR
				4444	4444	4444	4444	2430	0311	2000	
				4444	4444	4444	4444	3043	0220	1000	
			60 min	4444	4444	4444	4444	3403	0201	0000	NR
				4444	4444	4444	4444	4442	0202	0000	
				4444	4444	4444	4444	3434	0010	1100	
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC	CCCC	CCCC	CCCC	CCCC	0C0C	0000	NR
				CCCC	CCCC	CCCC	CCCC	CCCC	CC0C	0C00	
				CCCC	CCCC	CCCC	CCCC	0CCC	C000	0C00	
			Cells treated	CCCC	CCCC	CCCC	CCCC	C0CC	0C00	0000	NR
				CCCC	CCCC	CCCC	CCCC	CC0C	C0CC	0000	
				CCCC	CCCC	CCCC	CCCC	CCC0	00C0	0000	
Effectiveness control of the disinfectant detection activity	NA	0.3 g/L BSA	Without sample	CCCC	CCCC	CCCC	CCCC	CCCC	C00C	0000	NR
				CCCC	CCCC	CCCC	CCCC	CCCC	C0C0	000C	
				CCCC	CCCC	CCCC	CCCC	CCCC	0CCC	0000	
			With sample	CCCC	CCCC	CCCC	CCCC	CCCC	0C00	0000	NR
				CCCC	CCCC	CCCC	CCCC	CCCC	C0C0	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	0C00	00C0	

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.

C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).

0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline.

sec: seconds; min: minutes.

*: see Special remarks to understand the values of these concentrations.

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Date: 13.09.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17899/21/ROBCH/Z1
Table 5. Results of activity of the test sample, with Murine Norovirus, strain S99 Berlin, under test conditions requested by the client.

Assay	Concentration*	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after.....				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 min	
Test sample	80%	0.3 g/L BSA	0.5	-	0.50	-	-	$\geq 5.66 \pm 0.34$
	3%		0.5	-	3.99	-	-	2.17 ± 0.48
	0.03%		0.5	-	6.07	-	-	0.09 ± 0.53
Virus control	NA	0.3 g/L BSA	NA	6.25	6.16	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.5	NR	NR	4.24	2.66	NA
Virus control Formaldehyde	0.7% (w:v)	NA	0.5	6.41	NR	NR	6.25	NA
Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells)log ₁₀ ^{-0.50} 0 Control of the effectiveness of the disinfectant detection activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension).....log ₁₀ ^{-0.33}								
NA: not applicable; NR: not realized Times recommended by Standard for surfaces: maximum 5 or 60 minutes Times recommended by Standard for instruments: maximum 60 minutes Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds. PBS: phosphate buffered saline; BSA: bovine serum albumin. Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log. *: see Special remarks to understand the values of these concentrations.								

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17899/21/ROBCH/Z1

Table 6. Results of the activity of the test sample, with Murine Norovirus strain S99 Berlin (Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concentration *	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}								
				1	2	3	4	5	6	7	8	
Test sample	80%	0.3 g/L BSA	60 sec	0000	0000	0000	0000	0000	0000	0000	NR	
				0000	0000	0000	0000	0000	0000	0000		
				0000	0000	0000	0000	0000	0000	0000		
	3%		60 sec	4444	4444	4444	3000	0001	0000	0000	NR	
				4444	4444	4444	2303	0000	0000	0000		
				4444	4444	4444	0040	0000	0000	0000		
	0.03%		60 sec	4444	4444	4444	4444	3443	0200	0011	NR	
				4444	4444	4444	4444	4203	2012	0000		
				4444	4444	4444	4444	4434	0302	0000		
Cytotoxicity	80%	0.3 g/L BSA	NA	0000	0000	0000	0000	0000	0000	0000	NR	
Virus control	NA	0.3 g/L BSA	0	4444	4444	4444	4444	3444	2011	0000	NR	
				4444	4444	4444	4444	2334	2201	0000		
				4444	4444	4444	4444	4434	3201	0000		
			60 sec	4444	4444	4444	4444	4444	3000	0001	NR	
				4444	4444	4444	4444	4444	4403	0000		
				4444	4444	4444	4444	4444	0234	0000		
Formaldehyde	0.7% (w:v)	NA	30 min	4444	4444	4444	3430	0001	0000	0000	NR	
				4444	4444	4444	4203	0000	0000	0000		
				4444	4444	4444	0220	0000	0000	0000		
			60 min	4444	3320	0100	0010	0000	0000	0000	NR	
				4444	3223	2000	0100	0000	0000	0000		
				4444	0442	0110	0000	0000	0000	0000		
Control of formaldehyde cytotoxicity	0.7% (w:v)	0.3 g/L BSA	NA	0000	0000	0000	0000	0000	0000	0000	NR	
Virus control formaldehyde	0.7% (w:v)	NA	0	4444	4444	4444	4444	4444	3004	0010	0000	NR
				4444	4444	4444	4444	4444	0320	0002		
				4444	4444	4444	4444	4444	3330	0021		
			60 min	4444	4444	4444	4444	4444	0303	0010	0000	NR
				4444	4444	4444	4444	4444	0404	0020		
				4444	4444	4444	4444	4444	3200	1000		
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC	CCCC	CCCC	CCCC	CCCC	C000	000C	NR	
				CCCC	CCCC	CCCC	CCCC	CCCC	CC0C	00C0		
				CCCC	CCCC	CCCC	CCCC	CCCC	0CC0	0000		
			Cells treated	CCCC	CCCC	CCCC	CCCC	CCCC	CC0C	00C0	0000	NR
				CCCC	CCCC	CCCC	CCCC	CCCC	00CC	0000		
				CCCC	CCCC	CCCC	CCCC	CCCC	0000	0000		
Effectiveness control of the disinfectant detection activity	NA	0.3 g/L BSA	Without sample	CCCC	CCCC	CCCC	CCCC	CCCC	C00C	0000	NR	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCC0	0C0C		
				CCCC	CCCC	CCCC	CCCC	CCCC	CCC0	0000		
			With sample	CCCC	CCCC	CCCC	CCCC	C0CC	0C00	00C0	NR	
				CCCC	CCCC	CCCC	CCCC	C0CC	CC0C	00C0		
				CCCC	CCCC	CCCC	CCCC	CCC0	0CCC	0000		

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture; or grade of cellular lesions in the cytotoxicity assay.

C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same)

0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable;

NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline;

sec: seconds; min: minutes

*: see Special remarks to understand the values of these concentrations.

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Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

Figure 1. Results of the activity of the test sample under test conditions requested by the client with Poliovirus type 1 (ATCC VR-192).

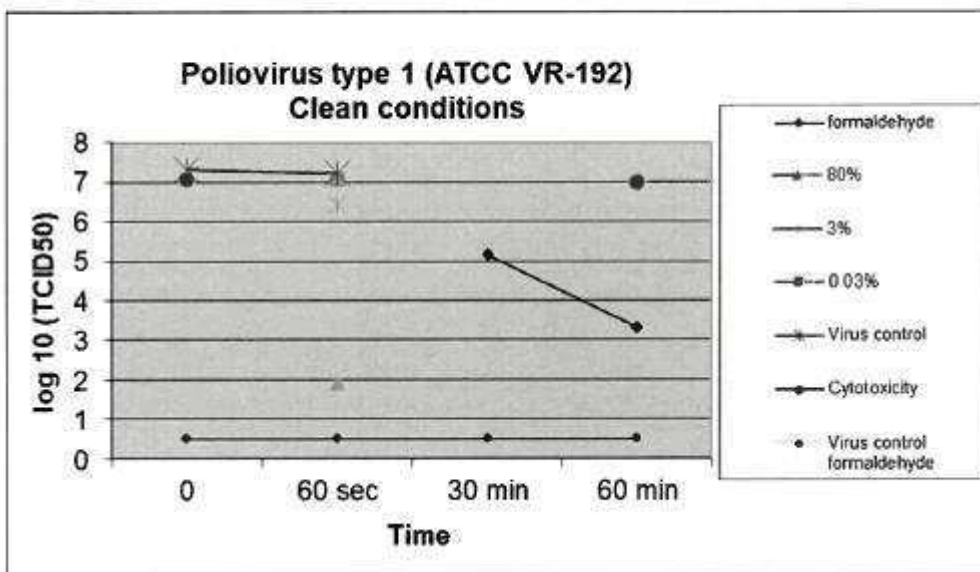
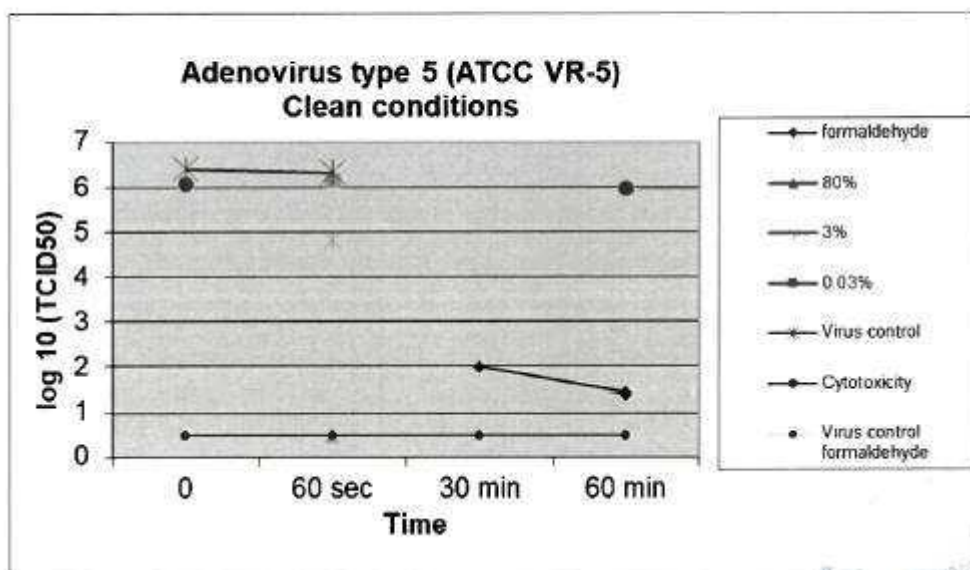


Figure 2. Results of the activity of the test sample under test conditions requested by the client with Adenovirus type 5 (ATCC VR-5).



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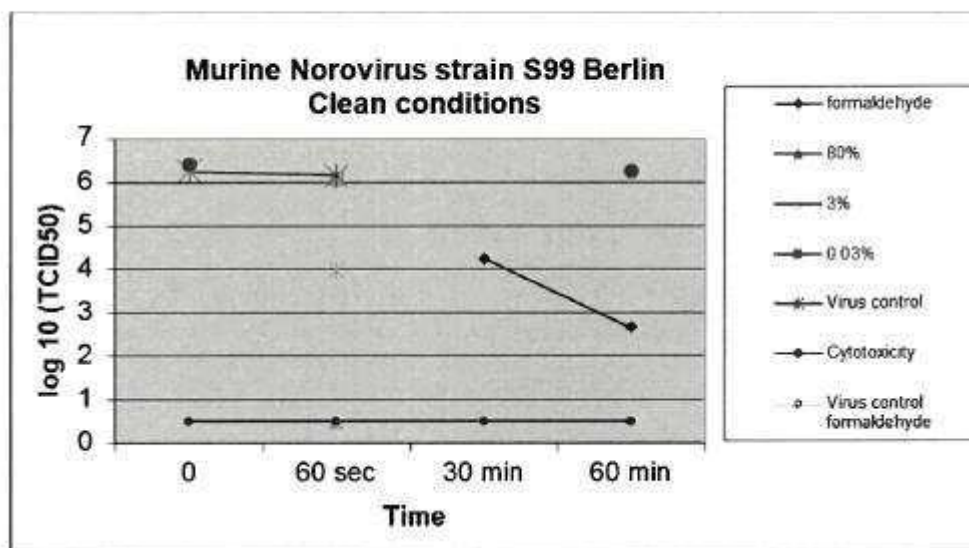
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Figure 3. Results of the activity of the test sample under test conditions requested by the client with Murine Norovirus strain S99 Berlin.



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