SUMMARY OF CLINICAL TEST

- The test was carried out in the “Dr Victor Babes” Hospital of Infectious and Tropical Diseases in Bucharest by the company SC Sante International SA
- The “Dr Victor Babes” Hospital of Infectious and Tropical Diseases in Bucharest is one of the largest hospitals of infectious diseases in Romania. Within the hospital clinical activity in applied medical research, didactic and scientific activity, work on medical assistance and combating epidemics is carried out at the highest scientific and professional standards and with the highest level of quality of the services.
- The study evaluated the effectiveness of the NOVAERUS air purification system, which is based on plasma.
- During the study, which was carried out over a period of 30 days, 232 air samples were taken from 6 locations.
- The study was supervised by Dr Maria Nica, Primary Laboratory Doctor, Head of the Laboratory of Clinical Microbiology at the hospital, with the participation of Dr Amalia Dascalu, Primary Laboratory Doctor in the same laboratory.

KEY FINDINGS

- The hospital staff found the NOVAERUS air purification system to be perfectly tolerable and easy to use.
- In the case of the air samples collected in the period of operation of the system, the number of colony-forming units was up to 96% lower than in the case of air samples collected before the system started to be used for both bacteria and fungi.

TEST REPORT

Evaluation of the NOVAERUS NV 200 and NV 800 air purification systems

Current phase of the test:	Complete
Product tested:	Novaerus air purification system based on plasma, models NV 200 and NV 800
Location in which the test was carried out:	The “Dr V. Babes” Hospital of Infectious and Tropical Diseases in Bucharest
Test coordinator from the hospital:	Dr Maria Nica – Primary Laboratory Doctor and Head of the Laboratory of Clinical Microbiology Dr Amalia Dascalu – Primary Laboratory Doctor
Company:	SC Sante International SA – Bd. Mihai Bravu no. 7, Sector 2, Bucharest
Person from the company responsible for the test:	Teodora Dragu – Product Manager Vitorio Mihai – Sales Manager
Period in which the test is carried out:	20 November – 23 December 2014
Date of report:	20 January 2015

1. SUMMARY

Title of the study: Evaluation of the Novaerus model NV 200 and NV 800 air purification systems

Entity carrying out the test: SC Sante International SA

Test locations: Medical and administrative areas at the “Dr V. Babes” Hospital of Infectious and Tropical Diseases in Bucharest

Test period: 20 November – 23 December 2014

Objectives:

- Evaluation of the effect of the air purification system on the microbial load of the ambient air
- Comparison of the effectiveness of the purification system over the test period
- Evaluation of the ease of use of the system and the tolerance of this in the environment

2. METHODOLOGY:

The test was carried out in the “Dr V. Babes” Hospital of Infectious and Tropical Diseases in Bucharest to evaluate the effectiveness of the Novaerus model NV 200 and NV 800 air purification systems.

The test was carried out in practical and current activity conditions and involved three stages:

1. Selecting test zones/locations and establishing the number of Novaerus systems needed

The test locations were determined by mutual agreement between the hospital management and S.C. Sante International SA team.

Six locations were used in the department of financial accounting, laboratory of clinical microbiology and ICU as follows:

- Department of financial accounting – 1 location
- Laboratory of clinical microbiology: 2 locations (Mycobacteria diagnostic laboratory and annex to this room in which samples are stored from the Mycobacteria diagnostic laboratory)
- ICU: 3 locations (patient room no. 1, ICU emergency laboratory and room for medical staff)

The number of Novaerus systems used for the test was established by the SC Sante International SA team depending on the volume of the location and the degree of risk of the area in which the systems were installed.

Eight systems were installed for the test, as follows:

- Department of financial accounting (dimensions of the room l x w x h: approx. 6 x 6 x 4 m; room volume approx. 144 m^3) – 2 Novaerus NV 800 systems
- Mycobacteria diagnostic laboratory (dimensions of the room l x w x h: approx. 5 x 3 x 2.5 m; room volume approx. 37.5 m^3) – 1 Novaerus NV 800 system
- Annex for the storage of samples (dimensions of the room l x w x h: approx. 3 x 2 x 2.5 m; room volume approx. 15 m^3) – 1 Novaerus NV 200 system
- Patient room no. 1 ICU (dimensions of the room l x w x h: approx. 5 x 5 x 5 m; room volume approx. 125 m^3) – 2 Novaerus NV 800 systems

- Emergency ICU laboratory (dimensions of the room l x w x h: approx. 3.5 x 2 x 4 m; room volume approx. 28 m^3) – 1 Novaerus NV 200 system
- Room for ICU medical staff (dimensions of the room l x w x h: approx. 4 x 3 x 4 m; room volume approx. 48 m^3) – 1 Novaerus NV 800 system

The systems were installed on the walls at a height of approximately 2 m above the ground in locations with as few access routes (entrances/exits) as possible and preferably without a current flow and an excess of fresh air.

Each system was tested over a period of four weeks, broken down into two periods as follows:

Period 1	2 weeks	system on
Period 2	2 weeks	system off

2. Determination of the test points and the collection time

After choosing the locations for the test to be carried out and the systems to be installed, several individual fixed testing points were established, from which air samples were collected and which were marked on a flat surface.

An important criterion when determining the fixed testing points was the uniformity of these so representative samples of the air in the location selected for the test could be collected.

The fixed collection points were selected so as to not be too close to one another or in an area with direct current from air conditioning or other sources of possible pollution of the air in the room. The air samples were collected at the same time of day, between 2 p.m. and 4 p.m., as more intense activity (such as changing the bed linen) could cause a dramatic increase in the number of pathogenic agents in the air.

3. Methodology of the collection and processing of the samples

The number of fixed collection points for each location selected was as follows:

- Department of financial accounting – 5 fixed collection points
- Mycobacteria diagnostic laboratory – 5 fixed collection points
- Annex for the storage of samples – 2 fixed collection points
- Patient room no. 1 ICU – 5 fixed collection points
- Emergency ICU laboratory – 2 fixed collection points
- Room for ICU medical staff – 3 fixed collection points

Over the course of the 30 days during which the test was carried out, air samples were collected 4 times from each location selected.

CHRONOLOGY OF THE COLLECTION OF THE SAMPLES

	Day 0	Day 7	Day 14	Day 30
Test T0	Control sample			
Test T1		Immediate effect sample		
Test T2			Maintenance level sample	
Test T3				Negative control

The air samples were collected at four times:

- Time T0 – samples collected on day 1, before the machines are started, representing the initial level of biological load from which the measurement of the effectiveness of the Novaerus plasma system starts.
- Time T1 – samples collected on day 7 of the test being carried out (after the machines have been working for one week). These samples represent the immediate effect of the Novaerus plasma system on the level of bio-pathogenic load of the air.
- Time T2 – samples collected on day 14 (2 after the machines have been working for two weeks), representing the maximum level of reduction in colony-forming units which can be reached by the permanent use of the Novaerus plasma system in the test environment selected.

  Although the functioning of the Novaerus system will continue to reduce the level of bio-pathogenic load of the air in the test environment selected after this point, the bio-destructive effect of this system will have been sufficiently demonstrated after a period of 14 days of testing to be able to establish a *minimum* value for the reduction in the number of germs.

  After time T2, ALL of the systems were switched off, enabling the negative control to be able to be taken at time T3.

- Time T3 – samples collected on day 30 (two weeks after the systems were switched off), representing the negative control test, through which the potential relapse in the level of bio-pathogenic load to the values measured prior to installation of the air purification system can be evaluated.

METHODOLOGY OF THE COLLECTION OF SAMPLES: BACTERIA AND FUNGI

The selection of the location for the test to be carried out is particularly important. The entry of air into the room (doors, windows, air conditioning systems etc.) was taken into account when selecting the sample collection points.

In order to analyse the total number of bacterial and fungal colonies, the air samples (500 litres) were collected and filtered using the air testing equipment MAS-100 (Merck, Germany).

The culture media used were TSA (tryptone soya agar) for bacteria and Sabouraud glucose extract agar for fungi (provider = Merck, Germany).

The following standard protocol was observed for each collection:

1. The collection equipment was positioned in the location selected at a height of 1 m above the ground.
2. The volume of air desired for the sample was selected (500 litres).
3. The collection equipment and hands were disinfected using an isopropanol-based product.
4. A Petri dish containing the culture medium was introduced into the equipment.
5. The collection equipment was closed and sealed.
6. The collection equipment was activated.
7. Once the sample had been collected, the Petri dish was removed from the equipment, the sample was identified with all of the necessary data and placed in an isothermic refrigerator bag.

The samples were transported to the laboratory within no more than two hours of collection at a temperature of between +5º and -3ºC.

The samples were incubated at +36ºC for a period of five days in the case of bacteria and at +26ºC for a period of up to seven days in the case of fungi.

3. RESULTS OF THE LABORATORY TESTS

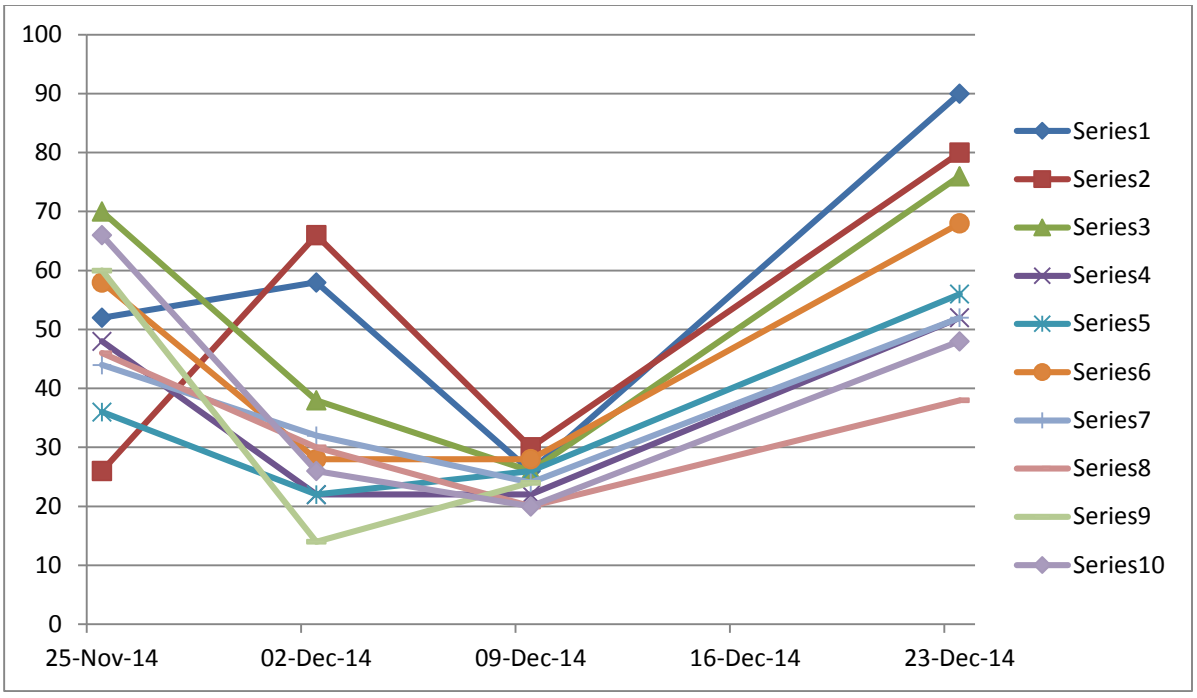
All of the samples collected were processed in the clinical microbiology laboratory at the "Dr V. Babes" Hospital of Infectious and Tropical Diseases in Bucharest.

The results of the test are set out in the tables below.

Table 1: Number of fungal CFUs in the ambient air samples

Location: ICU
Sample collection: filtration method
Culture medium: Sabouraud agar

	Number of CFUs T0 (Day 1)	Number of CFUs T1 (Day 7)	Number of CFUs T2 (Day 14)	Number of CFUs T3 (Day 30)
Location/collection point				
Emergency laboratory 1	52	58	26	90
Emergency laboratory 2	26	66	30	80
Doctors' room 3	70	38	26	76
Doctors' room 4	48	22	22	52
Doctors' room 5	36	22	26	56
Patient room 6	58	28	28	68
Patient room 7	44	32	24	52
Patient room 8	46	30	20	38
Patient room 9	60	14	24	54
Patient room 10	66	26	20	48

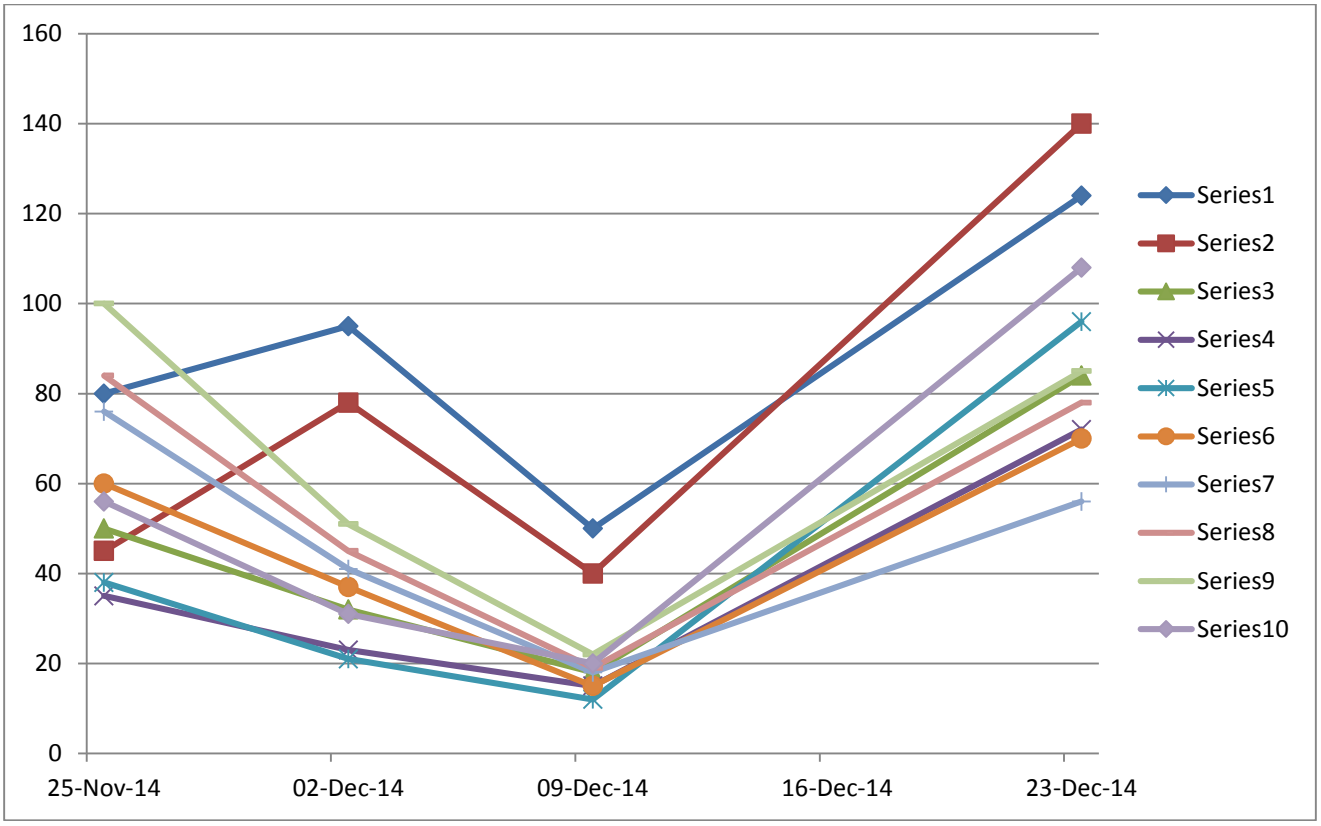


Over the course of the weeks T0-T1, in the ICU emergency laboratory the machine was accidentally covered with a deposit of sanitary material so it was unable to function under the appropriate conditions. The samples collected in points 1 and 2 at the time T1 presented elevated numbers of fungal CFUs.

Table 2: Number of bacterial CFUs in the ambient air samples

Location: ICU
Sample collection: filtration method
Culture medium: TSA

	Number of CFUs T0 (Day 1)	Number of CFUs T1 (Day 7)	Number of CFUs T2 (Day 14)	Number of CFUs T3 (Day 30)
Location/collection point				
Emergency laboratory 1	80	70	50	124
Emergency laboratory 2	45	78	40	140
Doctors' room 3	40	190	48	84
Doctors' room 4	35	166	50	72
Doctors' room 5	38	256	30	96
Patient room 6	60	96	60	70
Patient room 7	76	70	36	56
Patient room 8	84	124	38	78
Patient room 9	100	130	40	130
Patient room 10	56	90	20	108



Over the course of the weeks T0-T1, in the ICU emergency laboratory the machine was accidentally covered with a deposit of sanitary material so it was unable to function under the appropriate conditions. The samples collected in points 1 and 2 at the time T1 presented elevated numbers of bacterial CFUs.

Table 3: Number of fungal CFUs in the ambient air samples

Location: Department of financial accounting
Sample collection: filtration method
Culture medium: Sabouraud agar

	Number of CFUs T0 (Day 1)	Number of CFUs T1 (Day 7)	Number of CFUs T2 (Day 14)	Number of CFUs T3 (Day 30)
Collection point				
Point 1	68	46	20	40
Point 2	74	52	24	42
Point 3	60	36	16	26
Point 4	57	48	20	48
Point 5	69	60	20	30

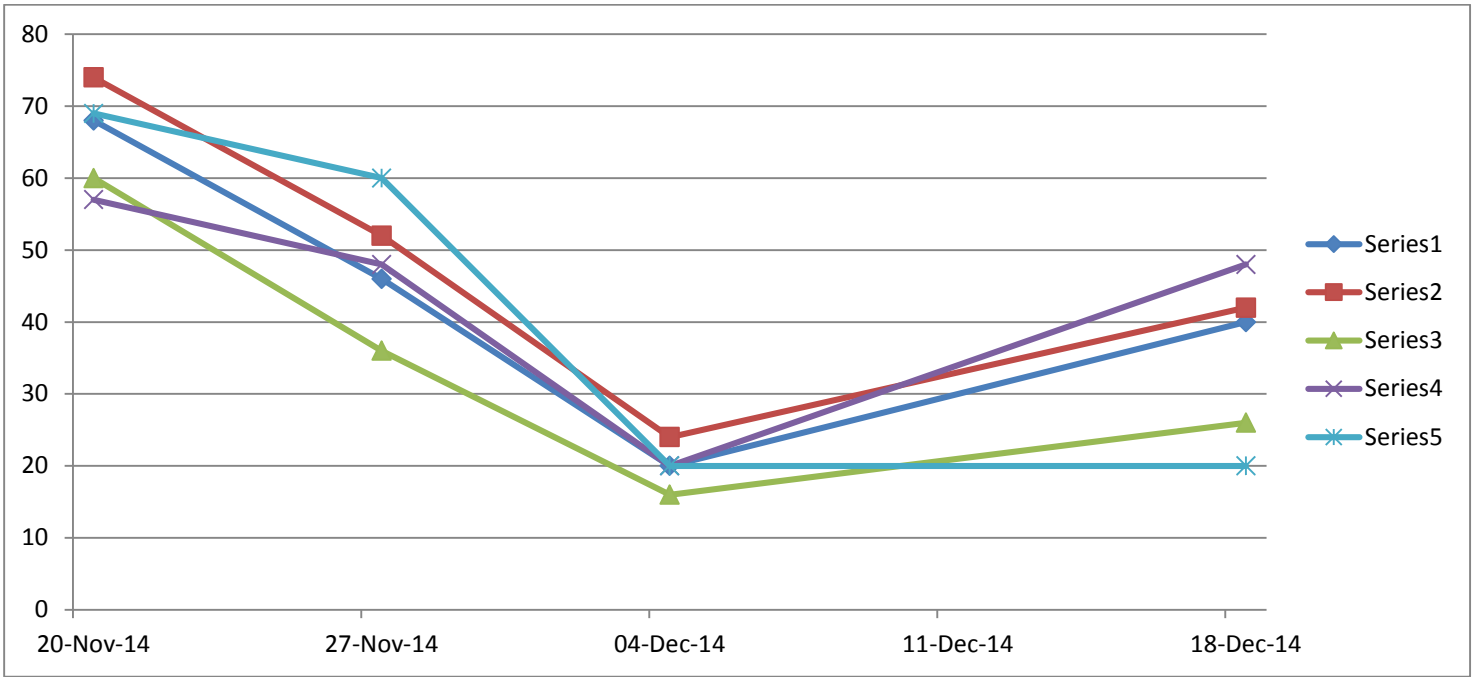


Table 4: Number of bacterial CFUs in the ambient air samples

Location: Department of financial accounting
Sample collection: filtration method
Culture medium: TSA

	Number of CFUs T0 (Day 1)	Number of CFUs T1 (Day 7)	Number of CFUs T2 (Day 14)	Number of CFUs T3 (Day 30)
Collection point				
Point 1	80	70	40	290
Point 2	95	75	20	300
Point 3	100	48	30	276
Point 4	105	60	40	220
Point 5	80	62	56	210

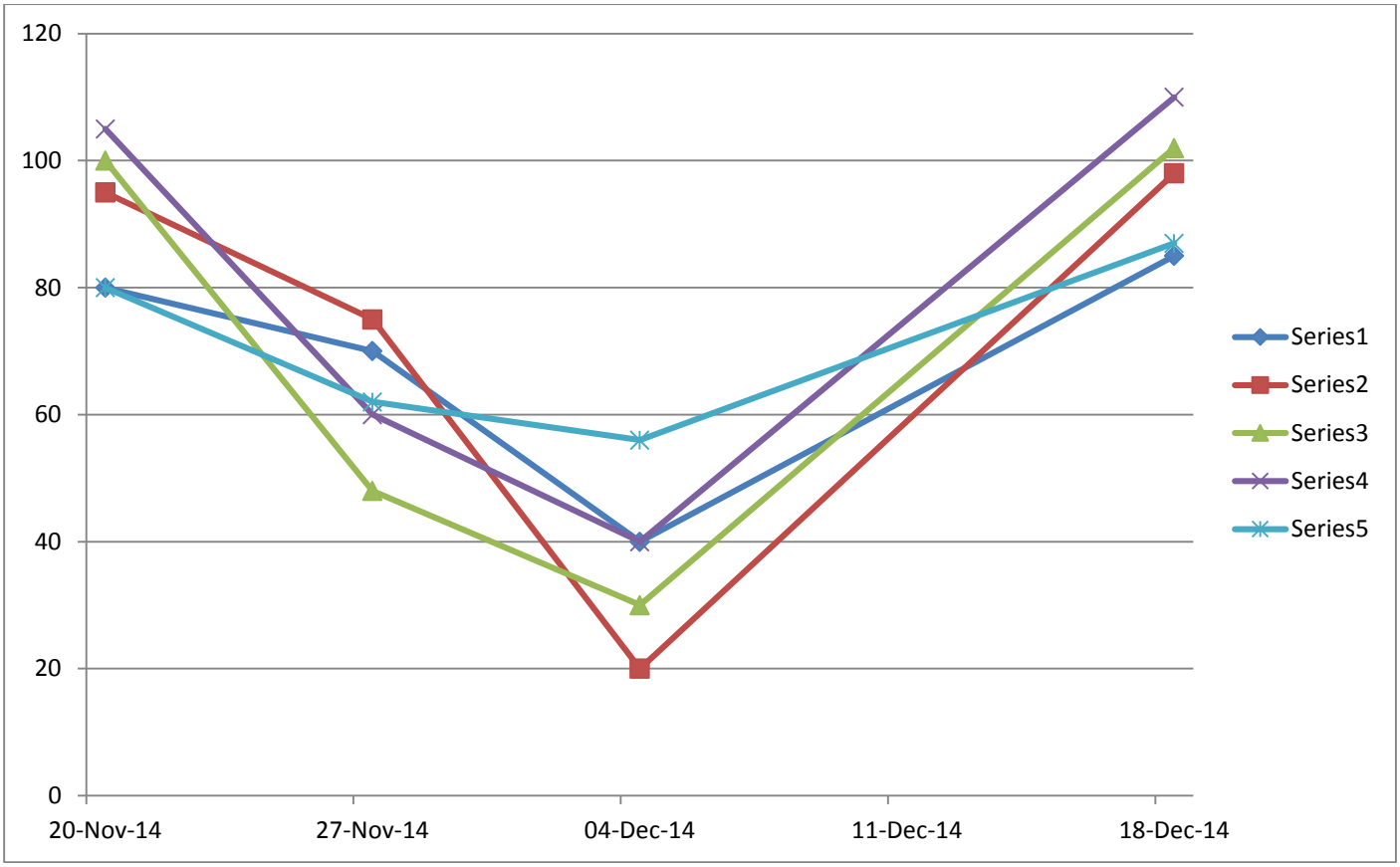


Table 5: Number of fungal CFUs in the ambient air samples

Location: Mycobacteria diagnostic laboratory
Sample collection: filtration method
Culture medium: Sabouraud agar

	Number of CFUs T0 (Day 1)	Number of CFUs T1 (Day 7)	Number of CFUs T2 (Day 14)	Number of CFUs T3 (Day 30)
Location/collection point				
MT laboratory 1	40	6	6	22
MT laboratory 2	30	12	12	16
MT laboratory 3	30	10	6	14
MT laboratory 4	20	6	6	12
MT laboratory 5	30	8	2	10
Room sample 1	25	10	6	18
Room sample 2	50	2	2	20

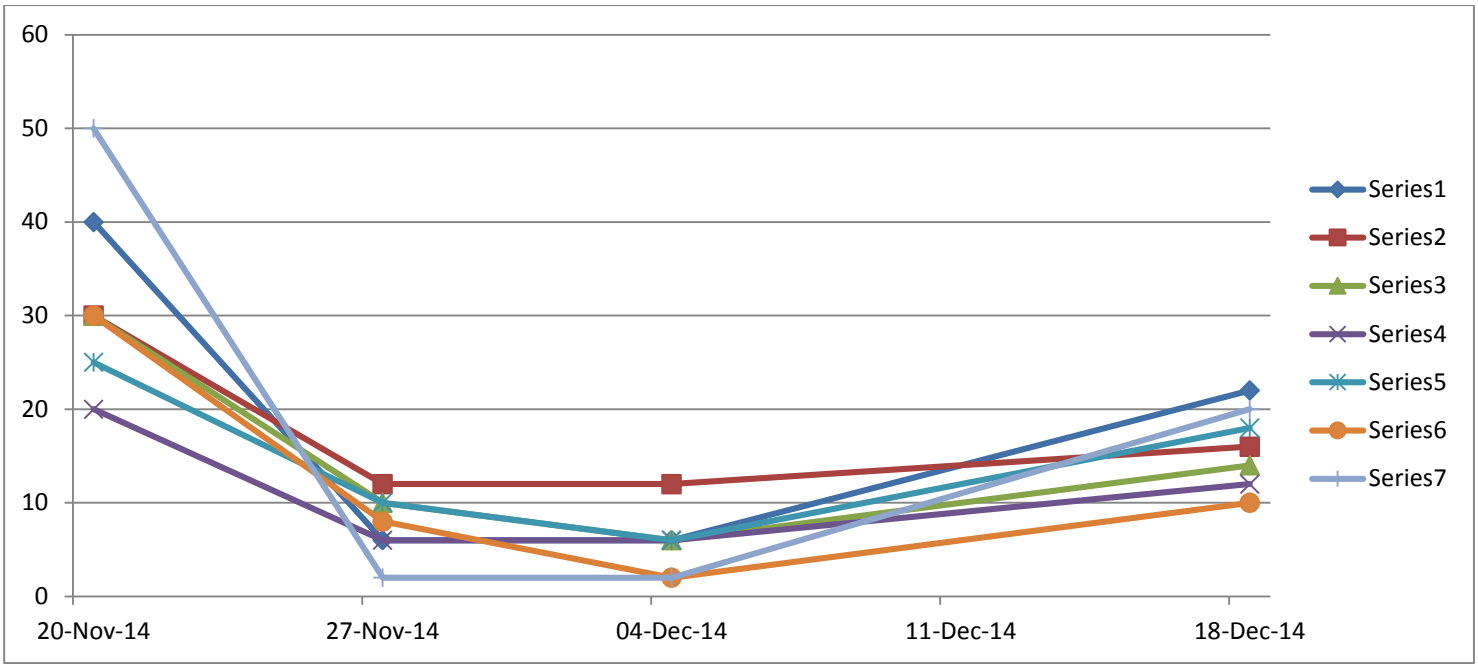


Table 6: Number of bacterial CFUs in the ambient air samples

Location: Mycobacteria diagnostic laboratory
Sample collection: filtration method
Culture medium: TSA

	Number of CFUs T0 (Day 1)	Number of CFUs T1 (Day 7)	Number of CFUs T2 (Day 14)	Number of CFUs T3 (Day 30)
Location/collection point				
MT laboratory 1	80	20	8	70
MT laboratory 2	85	16	14	58
MT laboratory 3	100	46	14	42
MT laboratory 4	100	20	16	36
MT laboratory 5	115	30	8	58
Room sample 1	95	38	16	32
Room sample 2	160	56	26	44

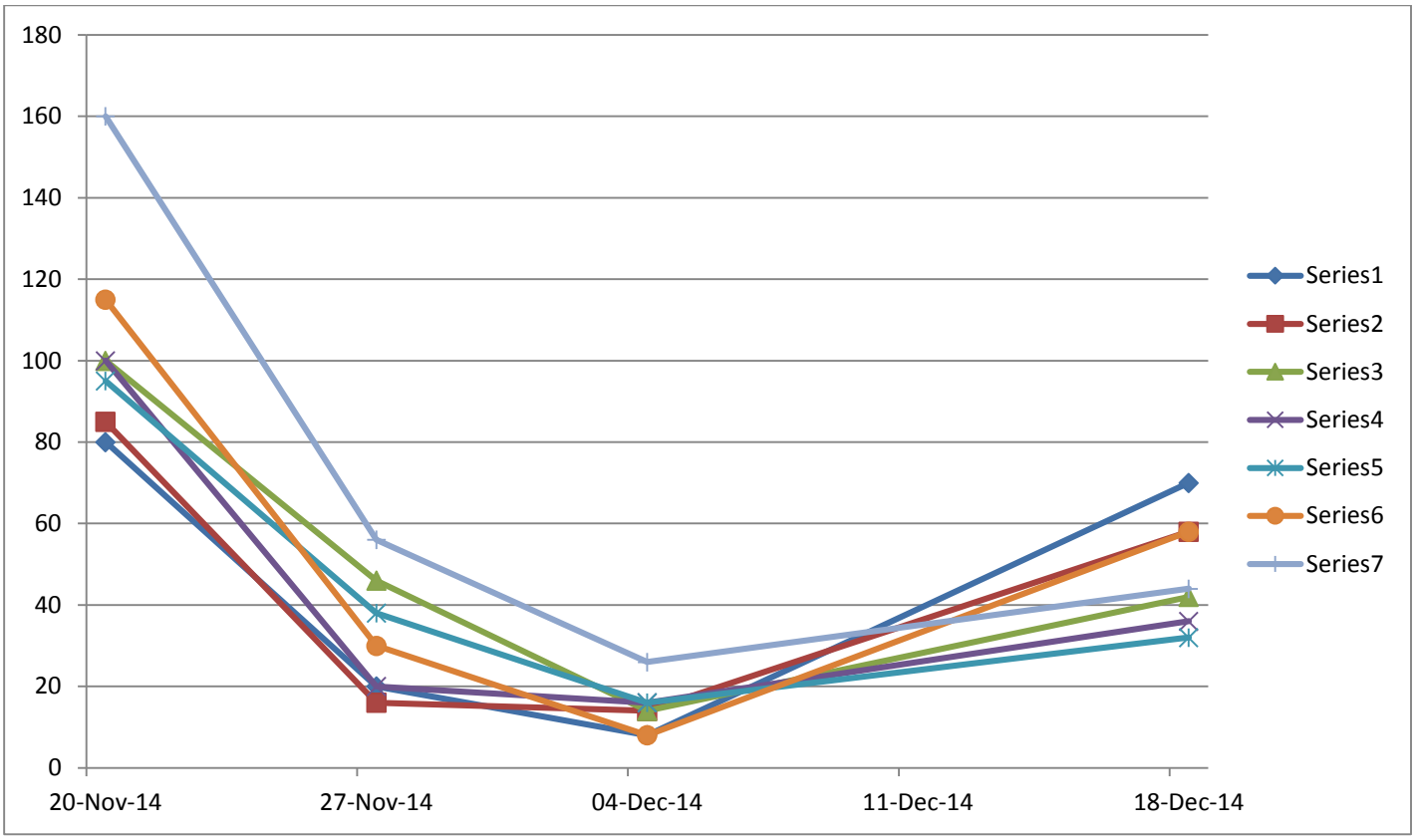


Table 7: Number of fungal CFUs in the ambient air samples

Location: Mycobacteria diagnostic laboratory
Sample collection: sedimentation method (Omeliansky formula)
Culture medium: Mueller-Hinton agar

	Number of colonies per dish T0 (Day 1)	Number of CFUs T0 (Day 1)	Number of colonies per dish T1 (Day 7)	Number of CFUs T1 (Day 7)	Number of colonies per dish T2 (Day 14)	Number of CFUs T2 (Day 14)	Number of colonies per dish T3 (Day 30)	Number of CFUs T3 (Day 30)
Location/collection point								
MT laboratory 1	4	282	3	211	1	70	2	141
MT laboratory 2	4	282	3	211	0	0	1	70
MT laboratory 3	3	211	2	141	1	70	3	211
MT laboratory 4	6	422	2	141	1	70	2	141
MT laboratory 5	5	352	2	141	0	0	2	141
Room sample 1	5	352	3	211	2	141	3	211
Room sample 2	5	352	3	211	2	141	3	211

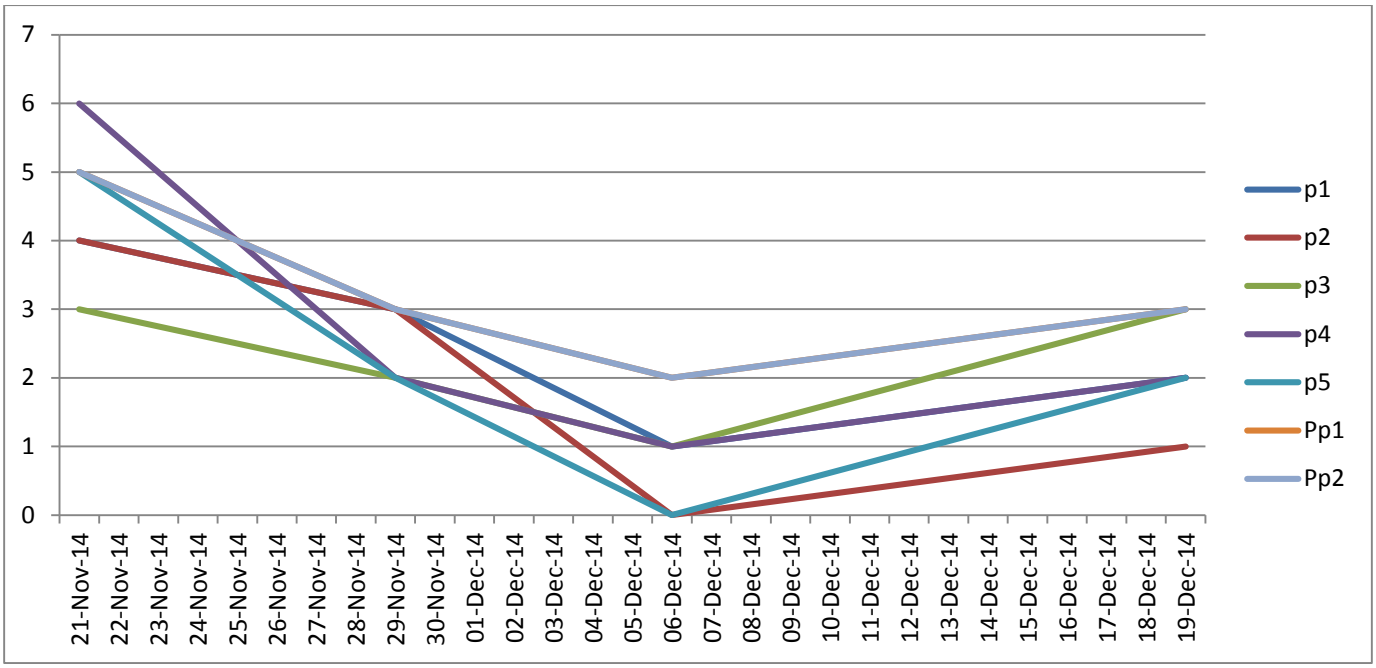
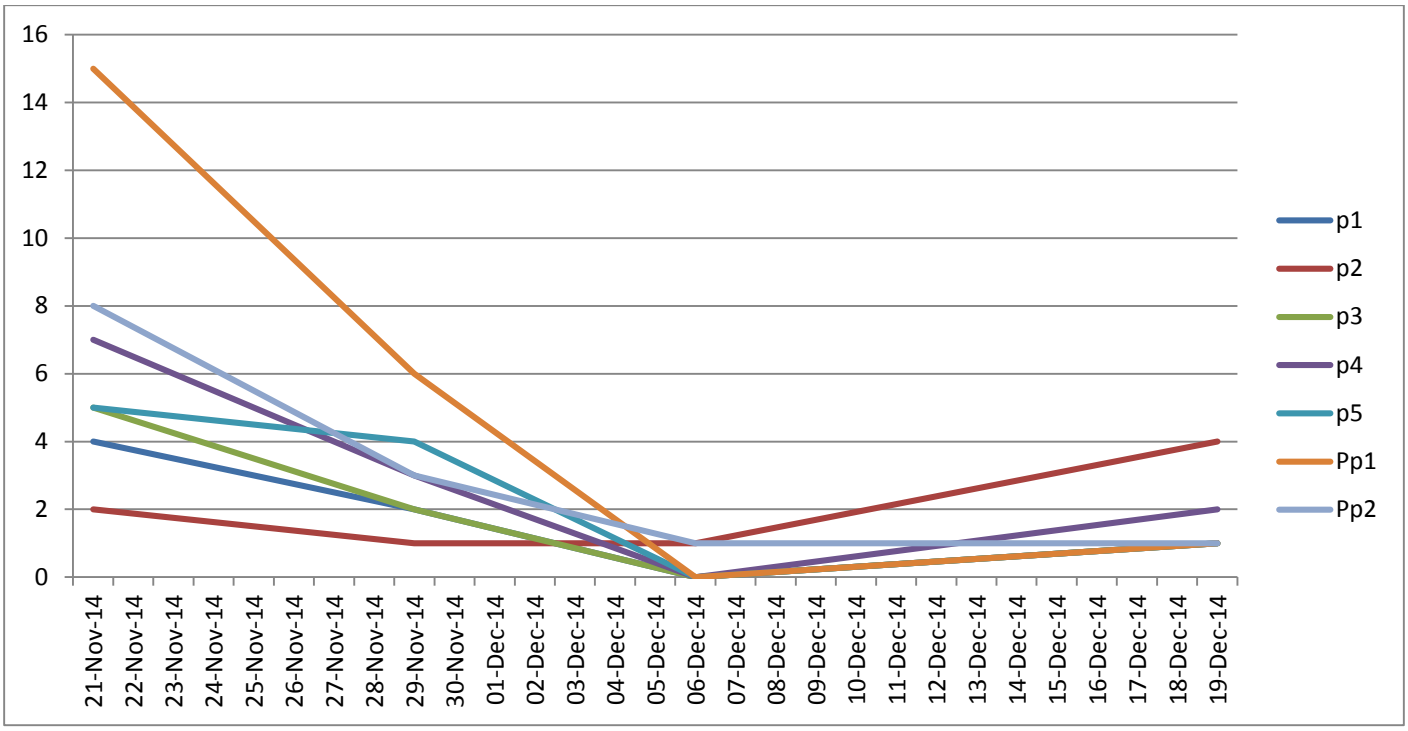


Table 8: Number of beta-haemolytic bacterial CFUs in the ambient air samples

Location: Mycobacteria diagnostic laboratory
Sample collection: sedimentation method (Omeliansky method)
Culture medium: Blood agar

	Number of colonies per dish T0 (Day 1)	Number of CFUs T0 (Day 1)	Number of colonies per dish T1 (Day 7)	Number of CFUs T1 (Day 7)	Number of colonies per dish T2 (Day 14)	Number of CFUs T2 (Day 14)	Number of colonies per dish T3 (Day 30)	Number of CFUs T3 (Day 30)
Location/collection point								
MT laboratory 1	4	282	2	141	0	0	1	70
MT laboratory 2	2	141	1	70	1	70	4	282
MT laboratory 3	5	351	2	141	0	0	1	70
MT laboratory 4	7	493	3	211	0	0	2	141
MT laboratory 5	5	352	4	282	0	0	1	70
Room sample 1	15	1056	6	422	0	0	1	70
Room sample 2	8	563	3	282	1	70	1	70



4. CONCLUSIONS

- In the case of the air samples collected during the period of operation of the system, the number of colony-forming units was up to *96% lower* than in the case of air samples collected before the system started to be used for strains of both bacteria and fungi.

- The hospital staff found the NOVAERUS air purification system to be: tolerable, easy to use and safe for patients and staff.

- The NOVAERUS air purification system complements existing measures to combat infections and does not require additional interventions to ensure that it functions without interruption.

- To obtain optimal results, the NOVAERUS air purification system should be used with continuous functioning without interruption under the conditions recommended by the manufacturer.

Date: 2 February 2015

SC SANTE INTERNATIONAL SA	"DR V BABES" HOSPITAL OF INFECTIOUS DISEASES
Person responsible for the study,	
Teodora Dragu	Dr Emilian Ioan Imbri
Product Manager	Manager
Vitorio Radu	Dr Maria Nica, Primary Laboratory Doctor
Sales Manager	Head of the Clinical Microbiology Laboratory
	Dr Amalia Oana Dascalu, Primary Laboratory Doctor