Introduction:

Endoscopes are widely used in current medical practice, both for diagnostic and therapeutic purposes and are procedures that currently involve virtually all medical specialties. Endoscopes are complex instruments and the procedures performed by them are increasingly invasive. (1) They evolved from instruments used to initially address mucous surfaces (digestive endoscopy, urology, respiratory, etc.) Digestive endoscopy is a minimally invasive procedure that is performed using a semi-critical medical device. Therefore, such medical devices require significant quality assurance for disinfection, as indicated by the Spaulding Classification, since flexible endoscopes can be highly contaminated with microorganisms, as they come into contact with secretions and mucous during use. In duodenoscopies, colonoscopies, gastroscopies, esophagoscopies, etc. and such narrow lumens and multiple internal channels make cleaning flexible endoscopes a complex but not impossible task to ensure the complete removal of these infectious agents.

Objectives: To verify the effectiveness of the disinfection process of endoscopes at the microbiological level with laboratory validation after being reprocessed with the Clean-Fast equipment

Material and method: Experimental descriptive study carried out in the gastroenterology service of a third-level clinic. 70 endoscopic were randomly selected in which microbiological tests were performed on 2 endoscopes per day for 35 days. Compliance with the guidelines of the World Gastroenterological Association in the reprocessing of endoscopes was observed and cultures were performed for common germs after reprocessing of the endoscope with the Clean-Fast equipment

Clean-Fast Features: Pump-free technological equipment for liquid compression which incorporates in its touch screen with the functions of: Leak test, cleaning, rinsing, disinfection and drying. Its innovative technological system provides an oscillatory irrigation inside generating a turbulent flow inside the endoscope channel to improve the scanning of microorganisms and reduce reprocessing time.

- Applicable Endoscopes: Flexible Endoscopes
- Washing method: Inside the channel
- Times:
  - Cleaning (Detergent): Minimum time 60sec
  - Rinse (Water): 30sec
  - Disinfection (Disinfectant): Time 330sec.
  - Drying (compressed air): 40sec

Electrical units

Electrical connection 110 V
Tolerance voltage +- 10%
Operating voltage 12 V
Current 4 Amp

The times established to irrigate and fill the channels of the endoscopes are

calculated according to the following equation:

$$V = \Pi\ h\ r^2$$

$$V = 3.14 \times 5 \times 1^2 = 15.7\ \mathbf{cm^3}$$

Tiempo de electroválvula

Tiempo On = 600 mseg x 25 = 15 segundos

Tiempo Off = 600 mseg x 25 = 15 segundos

25 = numero de irrigaciones

$$V_{total} = 25 \times 15.7 = 392.5\ \mathbf{cm^3}$$

$$V = 400\ cm^3$$

According to the above equation the Clean-Fast equipment delivers a minimum volume of 400 cm^3 in 30_{sec} which is a certain volume to irrigate the endoscope channels, the working pressure of the liquids is 20 Psi oscillatory pressure inside the endoscope channel to sweep the microorganisms, the drying pressure is 25 Psi. The contact times of the detergent and disinfectant are taken into account according to the recommendation of its manufacturer

Specifications.

Espc.
Applicable Endoscopes: Flexible Endoscopes
Washing method: Inside the channel
Washing times inside the channel
Washing and drying time 40 Sec
Detergent and drying time 40 sec hours Max.
Disinfection time 6 min – 1 hr. Max.
Air force time 10 sec – 30 sec Max
Dimension (mm): 230 (Width), X 400 (Height), X 90 (Depth).
Weight 4 Kg

Operating conditions
Temperature -5 / 70 °C
Humidity 0 – 80%
Operating pressure (compressed air) 0 – 4.13685 bar or 0 – 80 Psi

Connectivity
802.11.b/g/n/ac Dual-Band Wi-Fi 2.4 GHz
Gigabit Ethernet RJ45 300Mbps
4 USB 2.0 ports
5GHz Bluetooth 4.2

Guidelines and standards

The provision of safe and effective endoscopic services is governed by national and international standards that have many points in common, such as standards relating to facility design and staffing, automatic flexible endoscope reprocessors, disinfectants, water quality and drying cabinets.

The application of appropriate standards for reprocessing should respect the general principles of good manufacturing practice (GMP). GMP constitutes a set of regulations, codes and guidelines applicable to manufacturing/manufacturing processes – in this case those related to the reprocessing of endoscopes – to achieve high-level disinfection; covers both the process and quality control. GMPs are recognized worldwide for the control and management of manufacturing and quality control testing of pharmaceutical products, and have evolved over the past 60 years in response to a number of publicly known issues in the pharmaceutical industry [1].

While reprocessing instructions are often referred to as "guidelines", in fact, they are a technical standard that establishes the

minimum acceptable practice for reprocessing, to achieve high-level disinfection of endoscopes. Typically, medical guidelines address a limited clinical question using population-based data; they frequently use data from randomized trials to guide care for a particular patient. Randomized trials are conducted in specific populations, and clinicians must decide whether the guidelines are applicable to their particular patient [2].

The standards have a wider application and set specifications and procedures that are designed to ensure that products, services and systems are safe and reliable, and that they operate uniformly as they were designed. Supporting evidence for a standard is based on science, technology, and experience. It is not often that randomized trials are conducted in a particular population. The rules governing reprocessing have scientific basis, and are often validated by efficiency measurements in models using artificial dirt or known inocula of bacteria. The sciences of cleaning, disinfection, drying and microbiology form the basis of the relevant reprocessing standards in all countries.

Reprocessing procedure

The most important step in endoscope reprocessing is a scrupulous cleaning before disinfection. Without proper cleaning there will be no good disinfection [5–7].

The person in charge of cleaning is familiar with the structure of the endoscope and trained in cleaning techniques. Cleaningis doneimmediately after using the endoscope, to prevent the biological material from drying out and hardening. The detergents and cleaning equipment used (Clean-Fast) are suitables, and in particular n brushes with the right diameter for each channel are used. After cleaning, it is irrigated with the Clean-Fast thoroughly to ensure the elimination of all residues and detergents before disinfection.

1.2.1 Cleaning

Pre-cleaning: Immediately after each procedure, with the endoscope still attached to the light source, pass a lint-free disposable cloth through the insertion tube. Place the distal end in a medical-grade detergent solution that produces little foam and suck the detergent from all channels, including the aspirate and biopsy channel. Clean the air/water channels with detergent. All channels are irrigated first with water and then with air, including the jet channel, following the manufacturer's instructions. Washing air/water channels with detergent may require the use of a specific valve.

The endoscope is removed from the light source and brought to the cleaning area in a closed receptacle to prevent environmental contamination by drip or spillage; it is clearly indicated that the endoscope inside the receptacle is contaminated.

It is essential not to let the endoscope dry before proceeding with the cleaning,

because if the organic matter dries out it will become difficult or impossible to remove it. Endoscopes should be processed without delay, within the first 30 minutes.

Perform leak tests with Clean-Fast equipment to check the integrity of all channels before proceeding with processing. Remove all valves and buttons and test the instrument according to the manufacturer's instructions.

Brush and clean the buttons and valves, paying special attention to the internal surfaces, and high-level disinfection or sterilization is carried out following the original instructions of the equipment manufacturer.

The endoscope is immersed in a detergent solution in a pool in the "dirty" section of the decontamination area. The prepared detergent CIDEZYME 8 milliliters per liter is used. Brush to all accessible sections of the biopsy/aspiration channel following the manufacturer's instructions for use. Brush the tip and handles and clean the valve seats. Connect the irrigation channels to the cleaning hoses of the Clean-Fast equipment and on the touch, screen press the cleaning section so that the equipment begins with the irrigation of the channels, at the end of the irrigation of the detergent the Clean-Fast equipment start a drying process by passing pressurized air through the channels of the endoscope to evacuate the detergent from the channels of the endoscope.

Se rinses the endoscope to remove r the detergent, therefore, the endoscope is immersed in water and on the touch screen of the Clean-Fast the irrigation process begins which irrigates water in the channels of the endoscope and at the end of the irrigation process it will automatically start with the drying by passing pressurized air through the channels of the endoscope.

Detergent irrigation 30 seconds + 30 second contact + 40 second dryings. Liquid pressure = 20 Psi

Disinfection

The endoscope is immersed in the sinfectant solution in a pool in the "Clean" section of theinfection area. The prepared disinfectant CIDEX OPA 3.78 liters is used. The disinfection section is pressed on the touch screen of the *Clean-Fast* equipment so that the equipment begins with the irrigation of the channels, at the end of the irrigation of the disinfectant the Clean-Fast equipment will initiate a drying process by passing pressurized air through the channels of the endoscope to evacuate the disinfectant from the endoscope.

Irrigation of disinfectant 30 seconds + 300 second of contact + 40 second of drying. Liquid pressure = 20 Psi

Rinse and dry

The endoscope is immersed in water in a pool in the "Clean" section of theinfection area. The rinse section is pressed on the touch screen of the *Clean-Fast* equipment so that the equipment begins with the irrigation of the channels, at the end of the irrigation of the water the Clean-Fast equipment will initiate a drying process by passing pressurized air through the channels of the endoscope to evacuate

the water from the endoscope and perform the drying of the channels.

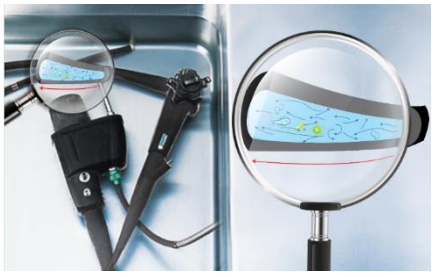
Water irrigation 30 seconds + drying 40 Second Pressure of the liquid inside the endoscope channel = 20 Psi

At the end of the reprocessing, the endoscope is placed in a cabinet.

Note. All essential steps of endoscope reprocessing should be documented to ensure quality and to enable patient tracking, if necessary.

The Clean-Fast incorporates a management software (EndoSoft) in which at the time of starting the reprocessing is registered:

- Who performs the reprocessing
- Date and time of reprocessing
- Identification of the reprocessed endoscope
- Environmental conditions (temperature and humidity)
- Disinfectant conditions (days of use)
- Processes carried out (leak test, cleaning, disinfection, drying).



Results.

Thanks to the Clean-Fast, it was possible to eliminate the use of syringes for the irrigation of the endoscope channels, positively impacting the physical health of the auxiliaries in charge of the reprocessing.

Reprocessing times were improved from 20 minutes to 15 minutes

The automatic system of the Clean-Fast guarantees an adequate and constant pressure and flow inside the endoscope channel, improving the scanning of microorganisms and guaranteeing safety to our patients.

Thanks to the EndoSoft software, it was possible to monitor and correct the endoscope assistants, as a result the training in the auxiliary 4 was reinforced in topics of the adequate reprocessing of endoscope and the care of these.

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VIGILADA MINEDUCACIÓN

USC UNIVERSIDAD SANTIAGO DE CALI

LABORATORIO DE METROLOGÍA

CERTIFICADO DE CALIBRACIÓN

R-RL001 Versión 5ª de Noviembre 28 de 2018

DATE OF PREPARATION OF THE CERTIFICATE	IDENTIFICATION NUMBER	NUMBER OF PAGES
2019-07-25 (Year / My / Day)	EG-15014-19 (CONSECUTIVE PREFIX YEAR)	1 OF 2

LABORATORY DATA

LABORATORY NAME	USC METROLOGY LABORATORY
PLACE WHERE CALIBRATION IS PERFORMED	LABORAORIO METROLOGIA USC

ADDRESS	LABORATORIES BLOCK (4) FLOOR 1	TELEPHONE	5183083
EMAIL	labmetrologia@usc.edu.co		

CUSTOMER DATA

Name Company	Ruvid	Night	1143939522
NAME CONTACT	FRANCISCO JAVIER ANGULO RENTERIA	Tel	3157754906
ADDRESS	MZ 1Z CS24 C 16C 36-68	CITY	Candelaria

COMPUTER INFORMATION AND ATTRIBUTES

TEAM	MARCH	MODEL	No. SERIES	SERVICE
Clean-Fast	RUVID	AM-II	201909-3	SURGE RY

METHOD INFORMATION

NAME OF THE PROCEDURE	ELECTRICAL SAFETY CALIBRATION	CODE	P-CL011

METHOD NAME	ANALYST	ITEMS TO BE CALIBRATED

ITEM	UNIT OF MEASUREMENT	BOSS	REMARKS
VOLTAGE	VOLT	ESA 620(FLUKE)	The tests performed are based on the NTC-IEC 60601 standard for electrocardiographs. According to the parameters of patient safety and techno surveillance.
STREAM	AMPS	ESA 620(FLUKE)	
RESISTANCE	OHMS	ESA 620(FLUKE)	

PATTERNS USED

TEAM	MARCH	MODEL	# SERIES	Traceability
A. ELECTRICAL SAFETY	FLUKE	ESA620	9779029	Certificate J13007-18 of 2018/07/30

USC UNIVERSIDAD SANTIAGO DE CALI
LABORATORIO DE METROLOGÍA

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DATE OF PREPARATION OF THE CERTIFICATE	IDENTIFICATION NUMBER	NUMBER OF PAGES
2019-07-25 (Year / My / Day)	EG-15014- 9 (CONSECUTIVE PREFIX YEAR)	2 OF 2

ELECTRICAL SAFETY CALIBRATION CERTIFICATE

HR%	54,0%
TEMP.	1980,0%

COMPLIANCE REPORT — Code R-CL011

ITEM		AVERAGE	DESV. STANDARD	FACTOR K	UNCERTAINTY	UNITS	NORM	Come in
1	LIVE TO NEUTRAL VOLTAGE	118,25	0,06	2,02	0,11	In	110 +/-10%	OK
2	NEUTRAL GROUND VOLTAGE	0,20	0,00	1,96	0,16	In	< 0.5	OK
3	LIVE VOLTAGE TO GROUND	119,60	0,23	2,57	0,34	In	110 +/- 15%	OK
4	GROUND LEAKAGE CURRENT	2,45	0,06	1,96	0,39	µA	≤ 500	OK
4.1	Condic.1st Open Neutral failure	9,70	0,08	1,96	0,40	µA	≤ 500	OK
4.2	INVERTED POLARITY	2,40	0,00	1,96	0,39	µA	≤ 500	OK
4.3	Condic.1st Open Neutral failure	9,60	0,00	1,96	0,39	µA	≤ 500	OK
5	LEAKAGE CURRENT TO CHASSIS	0,20	0,00	1,96	0,44	µA	≤ 100	OK
5.1	Condic.1st Open Neutral failure	0,10	0,00	1,96	0,39	µA	≤ 500	OK
5.2	Condic.2nd Open Earth Fault	0,10	0,00	1,96	0,39	µA	≤ 500	OK
6	INVERTED POLARITY	0,20	0,00	1,96	0,39	µA	≤ 500	OK
6.1	Condic.1st Open Neutral failure	0,10	0,00	1,96	0,39	µA	≤ 500	OK
6.2	Condic.2nd Open Earth Fault	0,10	0,00	1,96	0,39	µA	≤ 500	OK
7	LEAKAGE CURRENT OF APPLIED PARTS (ALL)	On	On	On	On	µA	≤ 10	On
7.1	Current leakage ELECTRODES	On	On	On	On	µA	≤ 10	On
7.11	Condic.1er Neutral open (all)	On	On	On	On	µA	≤ 500	On
7.12	Condic.2a Falla Tierra Abierta (all)	On	On	On	On	µA	≤ 50	On
7.13	INVERTED POLARITY (all)	On	On	On	On	µA	≤ 50	On
8	AUX CURRENT. ELECTRODES (all)**	On	On	On	On	µA	≤ 10	On
8.11	Condic.1er Linea abierta off (all)	On	On	On	On	µA	≤ 50	On
8.12	Condic.2a Inverted Polarity (all)	On	On	On	On	µA	≤ 50	On
10	Ground Resistance	0,09	0,00	1,96	0,01	Oh	≤ 0,2	OK

The data reported in this report correspond to the place and environmental conditions described herein.

NA: NO APPLIES

The limits of conformity of the measurements are taken from the technical standard NTC-IEC 60601 for electrocardiographs.

The standards used in this calibration have been compared to international standards certified by NIST.

end of certificate

METROLOGO

fernando charry

TECHNICAL DIRECTOR

Instituto para Niños Ciegos y Sordos del Valle del Cauca
Buscamos Luz en la Sombra y Palabra en el Silencio

Dra Mercedes Figueroa Macca

Bacteriología – Ciencias Básicas Médicas MSc, Ciencias Biomédicas PhD©
Universidad del Valle – Cali- Colombia

MICROBIOLOGICAL STUDY *CLEAN-FAST EQUIPMENT*

Date: 29/04/2019 Report: 29042019 11:00

Samples taken by Mercedes Figueroa Maca

Samples transported in Stuart Transport medium

1. Connectors of the newly reprocessed endoscope with the ***Clean-Fast equipment***
2. Control and controls of the newly disinfected endoscope with the ***Clean-Fast equipment***

Samples taken from washing with **tioglycolate** freshly disinfected with ***Clean-Fast equipment***.

1. **Tioglycate** in the **auxiliary channel of the** newly disinfected endoscope with the ***Clean-Fast equipment***

Microbiology Results Report

No.	Microbiological analysis	Analysis Technique	Result
1	Aerobic Plate Count	Plate count	**0 UFC**
2	Anaerobic Plate count	Plate count	**0 UFC**
3	Pseudomonas Aeruginosa Presence/Absence	Qualitative and Identification	**Negatively**
4	Gram Positive (Coagulasa Positive Staphylococcus)	Qualitative and Identification	**Negatively**
5	Total Coliforms	Plate count	**Negatively**
6	Fecal Coliforms	Plate count	**Negatively**
7	E. coli and Klebsiella	Identification	**Negatively**
8	Rescue from Thioglycolate	Identification	**Negatively**
9	Mold and Yeast Count	Identification	**Negatively**

Result: at 24, 48, 72 hours of incubation no bacterial growth **is observed**

Validated 29/04/2019 By:

Mercedes Figueroa Macca, MSc
Bacterióloga MSc, PhD©
Registro MinSalud: 20094

Fungal Culture

Result: at 30 days of incubation **no growth is observed** for Fungus

Validated 29/04/2019

Dra Mercedes Figueroa Macca
Bacterióloga Reg 20094
Universidad del Valle

Instituto para Niños Ciegos y Sordos del Valle del Cauca
Buscamos Luz en la Sombra y Palabra en el Silencio

Dra Mercedes Figueroa Macca
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Universidad del Valle – Cali- Colombia

MICROBIOLOGICAL STUDY *CLEAN-FAST EQUIPMENT*

Date: 26/04/2019 Report: 26042019 10:00

Samples taken by Mercedes Figueroa Maca

Samples transported in Stuart Transport medium

1. Connectors of the newly reprocessed endoscope with the ***Clean-Fast equipment***
2. Control and controls of the newly disinfected endoscope with the ***Clean-Fast equipment***

Samples taken from washing with **tioglycolate** freshly disinfected with ***Clean-Fast equipment***.

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Fungal Culture

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Validated 26/04/2019

Dra. Mercedes Figueroa Macca
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Instituto para Niños Ciegos y Sordos del Valle del Cauca
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Universidad del Valle – Cali- Colombia

MICROBIOLOGICAL STUDY *CLEAN-FAST EQUIPMENT*

Date: 25/04/2019 Report: 25042019 10:00

Samples taken by Mercedes Figueroa Maca

Samples transported in Stuart Transport medium

3. Connectors of the newly reprocessed endoscope with the ***Clean-Fast equipment***
4. Control and controls of the newly disinfected endoscope with the ***Clean-Fast equipment***

Samples taken from washing with **tioglycolate** freshly disinfected with ***Clean-Fast equipment***.

- **Tioglycate** in the **auxiliary channel of the** newly disinfected endoscope with the ***Clean-Fast equipment***

Microbiology Results Report

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6	Fecal Coliforms	Plate count	**Negatively**
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8	Rescue from Thioglycolate	Identification	**Negatively**
9	Mold and Yeast Count	Identification	**Negatively**

Result: at 24, 48, 72 hours of incubation no bacterial growth **is observed**

Validated 25/04/2019 By:

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Registro MinSalud: 20094

Fungal Culture

Result: at 30 days of incubation **no growth is observed** for Fungus

Validated 25/04/2019

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Instituto para Niños Ciegos y Sordos del Valle del Cauca
Buscamos Luz en la Sombra y Palabra en el Silencio

Dra Mercedes Figueroa Macca
Bacteriología – Ciencias Básicas Médicas MSc, Ciencias Biomédicas PhD©
Universidad del Valle – Cali- Colombia

MICROBIOLOGICAL STUDY *CLEAN-FAST EQUIPMENT*

Date: 24/04/2019 Report: 24042019 09:00

Samples taken by Mercedes Figueroa Maca

Samples transported in Stuart Transport medium

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Validated 24/04/2019

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Universidad del Valle – Cali- Colombia

MICROBIOLOGICAL STUDY *CLEAN-FAST EQUIPMENT*

Date: 29/04/2019 Report: 29042019-1 10:14

Samples taken by Mercedes Figueroa Maca

Name: HISOPO, EQUIPO CLEAN-FAST

Sampling 29/04/2019

STUDY NAME RESULT REFERENCE INTERVAL UNITS

RESULTS REPORT

CULTURE OF COMMON GERMS (DIFFERENT SAMPLES 0-0

Type of Examination: CULTIVATION OF COMMON GERMS

Sample Type: Swab

The result: Negative

Mercedes Figueroa Macca, MSc
Bacterióloga MSc, PhD©
Registro MinSalud: 20094

Validated 29/04/2019
Validated by: Mercedes Figueroa Maca, MSC

Dra Mercedes Figueroa Macca
Bacteriología – Ciencias Básicas Médicas MSc, Ciencias Biomédicas PhD©
Universidad del Valle – Cali- Colombia

MICROBIOLOGICAL STUDY *CLEAN-FAST EQUIPMENT*

Date: 26/04/2019 Report: 26042019-1 09:50

Samples taken by Mercedes Figueroa Maca

Name: HISOPO, EQUIPO CLEAN-FAST

Sampling 26/04/2019

STUDY NAME RESULT REFERENCE INTERVAL UNITS

RESULTS REPORT

CULTURE OF COMMON GERMS (DIFFERENT SAMPLES 0-0

Type of Examination: CULTIVATION OF COMMON GERMS

Sample Type: Swab

The result: Negative

Mercedes Figueroa Macca, MSc
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Registro MinSalud: 20094

Validated 26/04/2019
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Instituto para Niños Ciegos y Sordos del Valle del Cauca
Buscamos Luz en la Sombra y Palabra en el Silencio

Dra Mercedes Figueroa Macca
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Universidad del Valle – Cali- Colombia

MICROBIOLOGICAL STUDY *CLEAN-FAST* EQUIPMENT

Date: 25/04/2019 Report: 25042019-1 10:45

Samples taken by Mercedes Figueroa Maca

Name: HISOPO, EQUIPO CLEAN-FAST

Sampling 25/04/2019

STUDY NAME RESULT REFERENCE INTERVAL UNITS

RESULTS REPORT

CULTURE OF COMMON GERMS (DIFFERENT SAMPLES 0-0

Type of Examination: CULTIVATION OF COMMON GERMS

Sample Type: Swab

The result: Negative

Mercedes Figueroa Macca, MSc
Bacterióloga MSc, PhD©
Registro MinSalud: 20094

Validated 25/04/2019
Validated by: Mercedes Figueroa Maca, MSC

N. de Orden: 04050847

Laboratorio Clínico Especializado
nohemy cruz

www.nohemylab.com

Name: **Clean-Fast** Phone

Story**: 04050847** Age/Gender: 0 Day 1

Origin: Figueroa Maca Mercedes Date Created: **05/04/2019**

RESULT REPORT

RESULT NAME	UNITS	REFERENCE	INTERVAL STUDY

COMMON GERM CULTURES (DIFFERENT SAMPLES)

COMMON GERM CROPS (DIFFERENT SAMPLES)	**0 – 0**

NEGATIVE AFTER 72 HOURS OF INCUBATION

Responsable: Sandra Abou orm sab
Bacteriologa CC 704732
Fecha de Validación: 08/04/2019 02:15:33 p.

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