

Challenges in Highly Infectious Disease biobanking: The experience of the Biorepository of the National Institute for Infectious Diseases 'L. Spallanzani':

Antonino Di Caro

UOC Laboratorio di Microbiologia e Banca Biologica
Istituto Nazionale per le Malattie Infettive IRCCS 'L. Spallanzani'
Roma



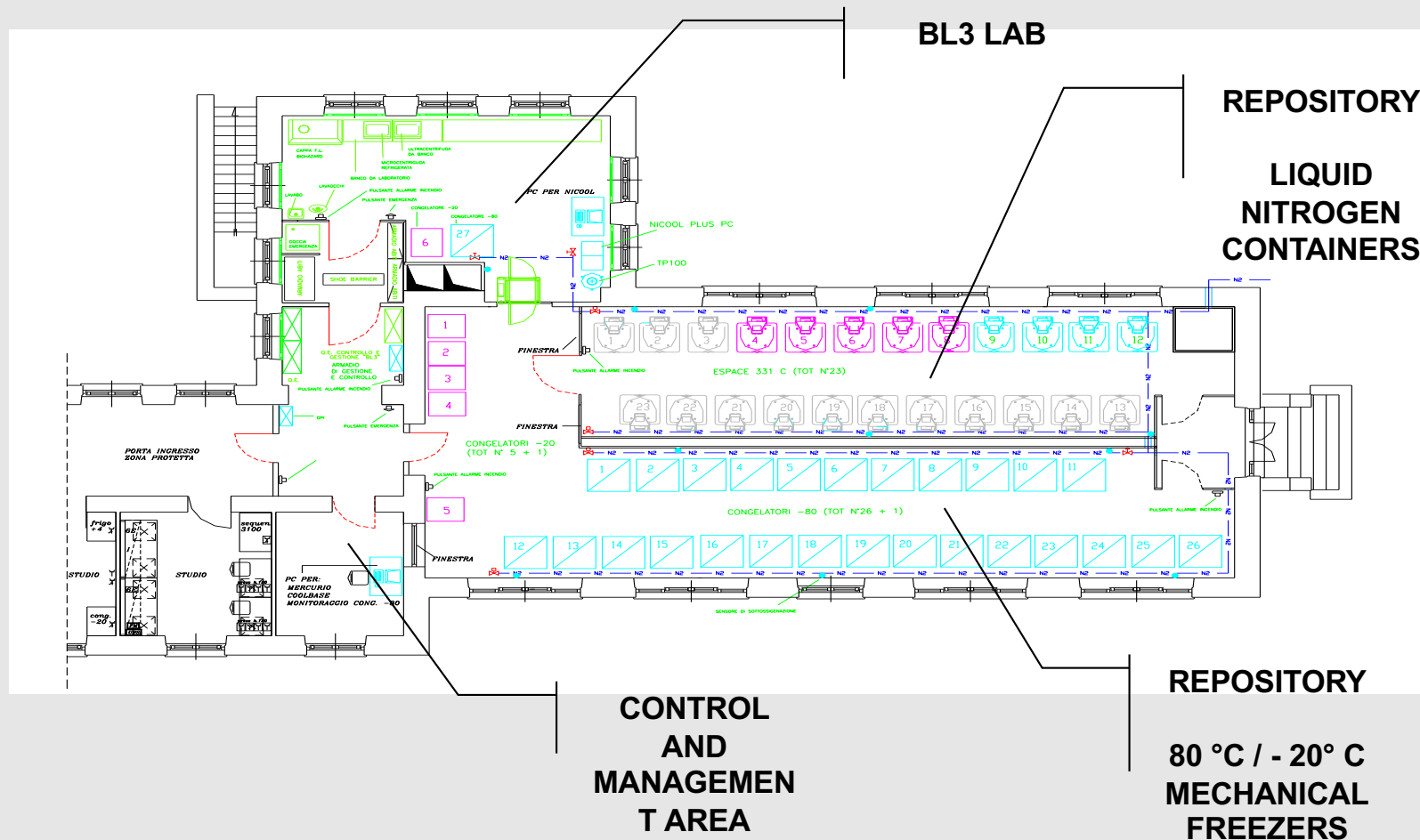
The National Institute for Infectious Diseases 'L. Spallanzani'- Italy

Special tasks

- National Reference Centre for emerging/reemerging viruses and bioterrorism
 - Patient care
 - high isolation capacity, high containment ambulances.
 - Laboratory Diagnostics
 - BSL-3/4 laboratories
 - Research and Training Centre
 - Epidemiological and clinical research on EIDs
- WHO Collaborating Centre for training, diagnosis, clinical care and response to Highly Infectious Diseases

The Biobank

- Sample collection started end '60s and increased consistently after AIDS epidemic (ICONA, 1997)
- Dedicated facility built in 2001
- Upgrading and formal recognition in 2003
- Certification **ISO 9001:2015 Quality** management systems (since 2004)
- Dedicated, full-time staff employed (2007-2008)
- Networking: BBMRI (2008), ERINHA (2011), EVA (2012) , MIRRI(2014 Italy)



Built on a surface of approx. 250 square metres, four main areas:

BSL-3 Laboratory	(50 m ²)
Repository – liquid nitrogen containers	(70 m ²)
Repository – mechanical freezers (-80 / -20°C)	(90 m ²)
Control and Management Area	(30 m ²)

Collected samples (March 31)

	N.
Urine	507
Stool	36
PBMC	500
PLASMA	1045
Serum	1106
Swabs	1474
Whole blood	8
CSF	4
BAL/ BAS	205
Patients	1756
Smples	2659
Aliquots	4885

INMI Biobank: Specific aspects

- **Biobank database interfaced with laboratory database and management system**
- **Regulation to collect residual samples and anonymize samples before processing and/or apply for ethical consent to Institutional Ethical Committee.**
- **Easy to adapt preformed informed consent form for rapid collection of samples in case of outbreak**
- **Training for the manipulation of Infectious diseases patients up to BSL3**
- **Possibility to upgrade procedure to BSL3.**

Why are we still working at enhanced BSL2?



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Laboratory biosafety guidance related to coronavirus disease 2019 (COVID-19)

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Overview

The purpose of this document is to provide interim guidance on laboratory biosafety related to the testing of clinical specimens of patients that meet the case definition of the novel pathogen identified in Wuhan, China, that is, coronavirus disease 2019 COVID-19.

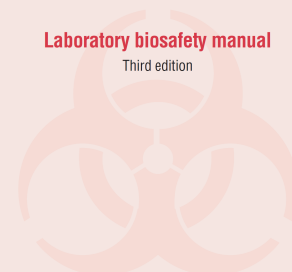


Table 2. Relation of risk groups to biosafety levels, practices and equipment

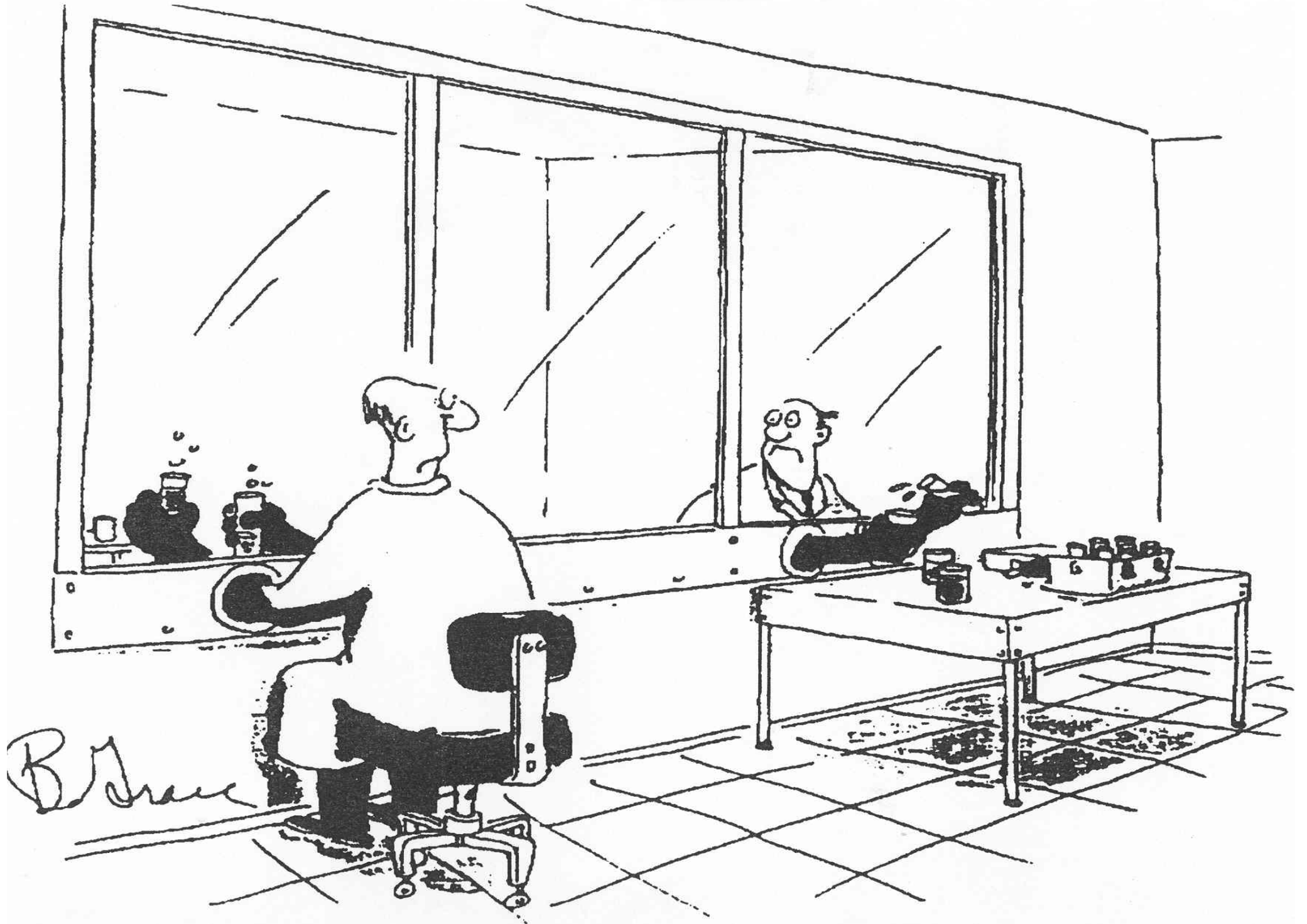
RISK GROUP	BIOSAFETY LEVEL	LABORATORY TYPE	LABORATORY PRACTICES	SAFETY EQUIPMENT
1	Basic – Biosafety Level 1	Basic teaching, research	GMT	None; open bench work
2	Basic – Biosafety Level 2	Primary health services; diagnostic services, research	GMT plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols
3	Containment – Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
4	Maximum containment – Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double-ended autoclave (through the wall), filtered air

BSC, biological safety cabinet; GMT, good microbiological techniques (see Part IV of this manual)

Highlights of COVID-19 laboratory biosafety

1. All procedures must be performed based on risk assessment and only by personnel with demonstrated capability, and **training**....
2. Initial processing (before inactivation) of all specimens should take place in a validated biological safety cabinet(**BSC II or more**)....
3. Non-propagative diagnostic laboratory work should be conducted at a facility using procedures equivalent to Biosafety Level 2 (**BSL-2**).
4. Propagative work (for example, virus culture, isolation or neutralization assays) should be conducted at a containment laboratory with inward directional airflow (BSL-3).
5. Appropriate **PPE** and **disinfectants** must be made available and HCW trained to use them

Non-culture-based diagnostic laboratory work on clinical specimens from patients who are suspected or confirmed to be infected with the virus responsible for COVID-19 should be conducted adopting practices and procedures described for conventional clinical and microbiology laboratories



Thank you!