NOVO CORONAVÍRUS
COVID-19

SITUAÇÃO EPIDEMIOLÓGICA EM PORTUGAL

5ª FEIRA, 16 DE SETEMBRO DE 2021

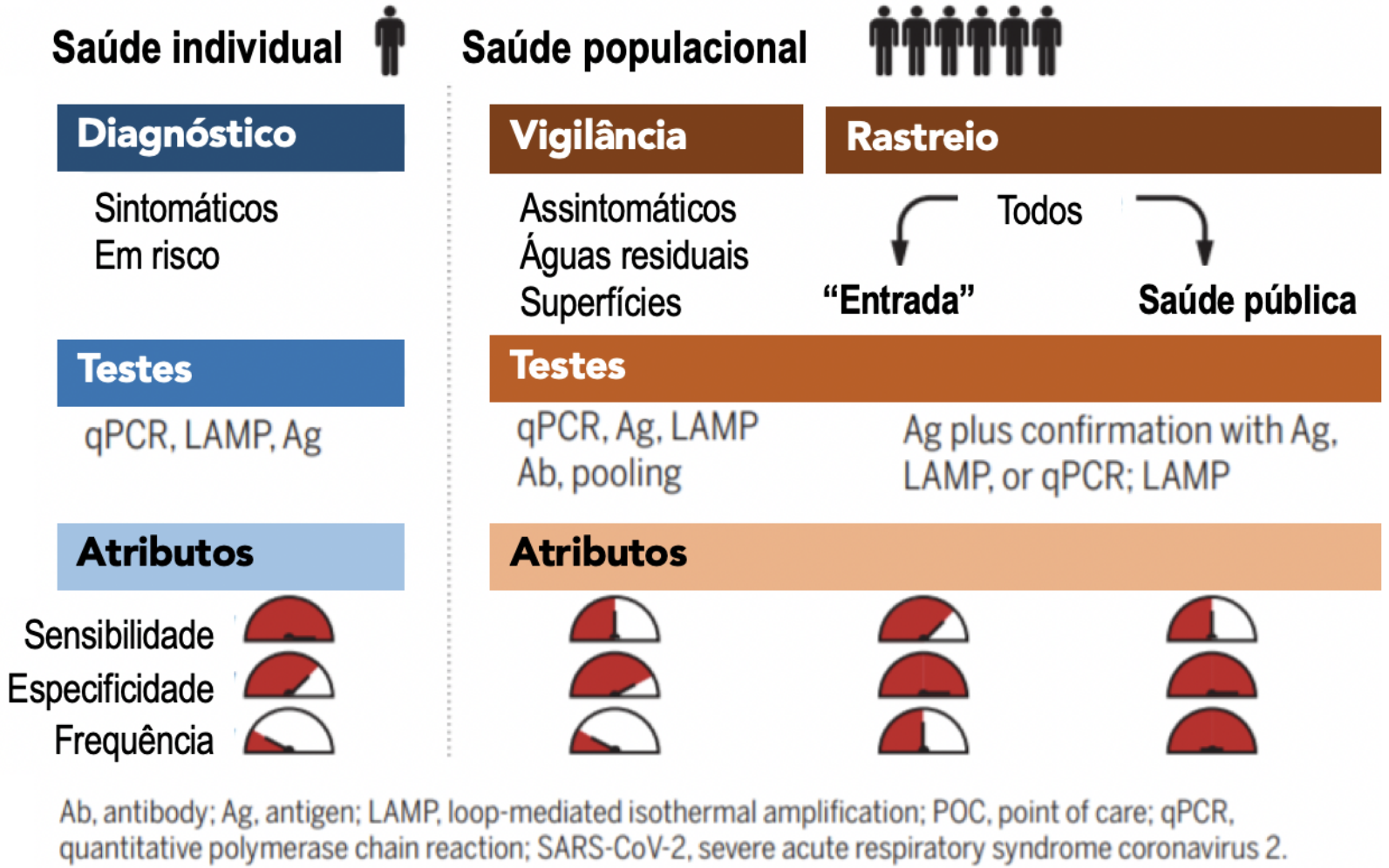
AUDITÓRIO INFARMED

TESTES E COVID-19: AS RESPOSTAS DA EPIDEMIOLOGIA

Milton Severo, Daniela Correia, Margarida Tavares, Ana Isabel Ribeiro, Teresa Leão, Paula Meireles, Henrique Barros

INSTITUTO DE SAÚDE PÚBLICA DA UNIVERSIDADE DO PORTO

ESTRATÉGIAS NA REALIZAÇÃO DE TESTES PARA INFEÇÃO POR SARS-CoV-2



Ab, antibody; Ag, antigen; LAMP, loop-mediated isothermal amplification; POC, point of care; qPCR, quantitative polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

Michael J. Mina and Kristian G. Andersen COVID-19 testing: One size does not fit all Science 371 (6525), 126-127

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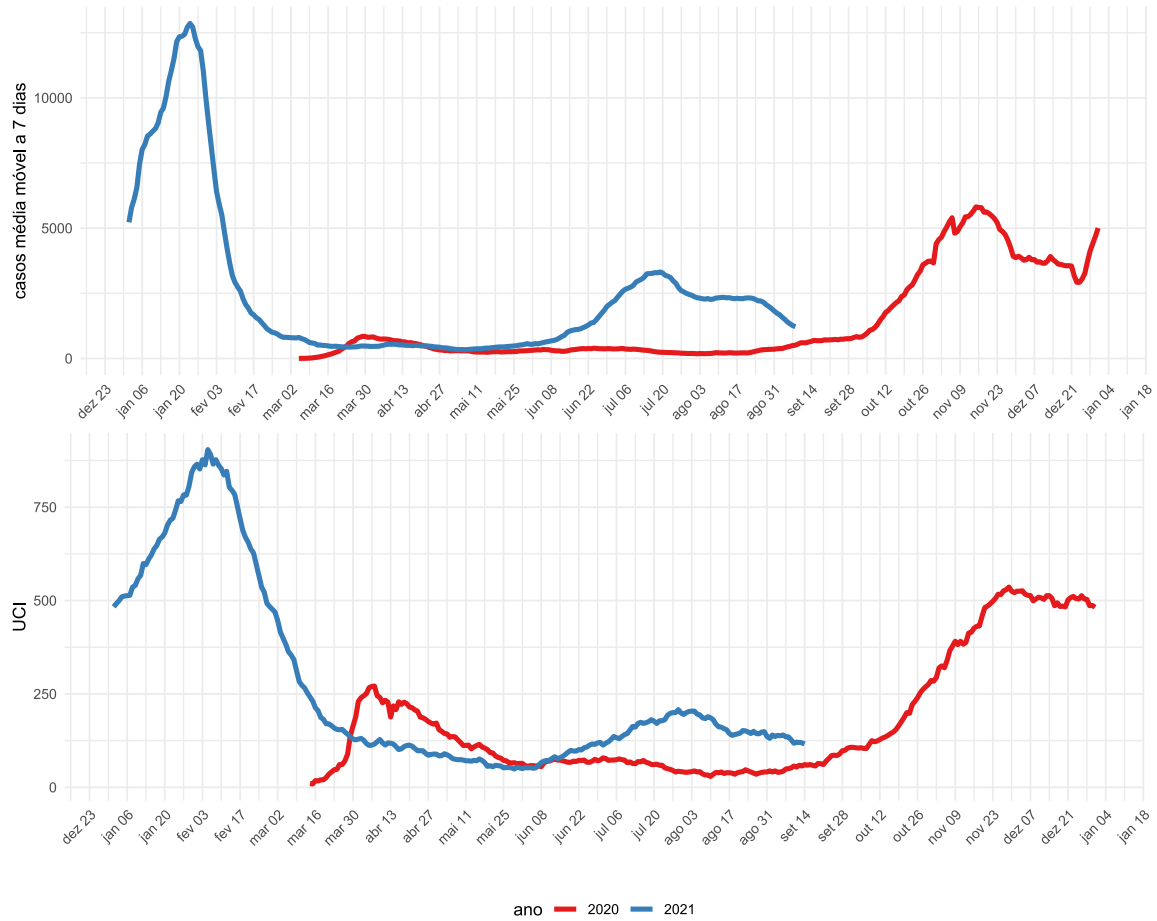
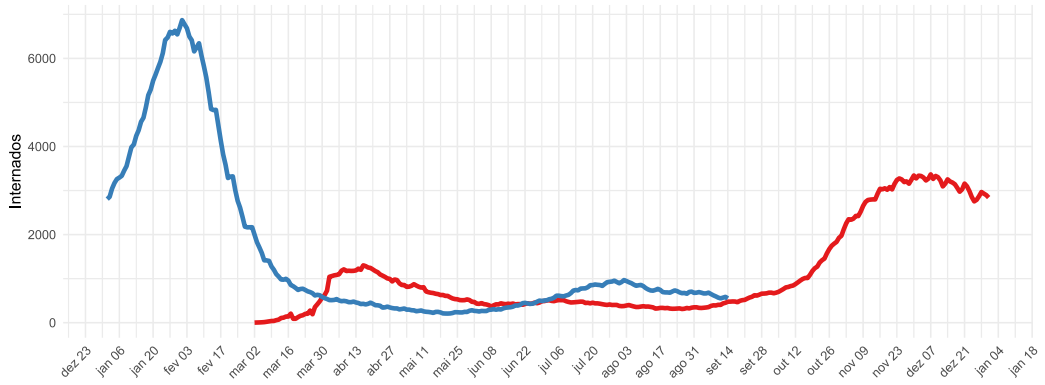
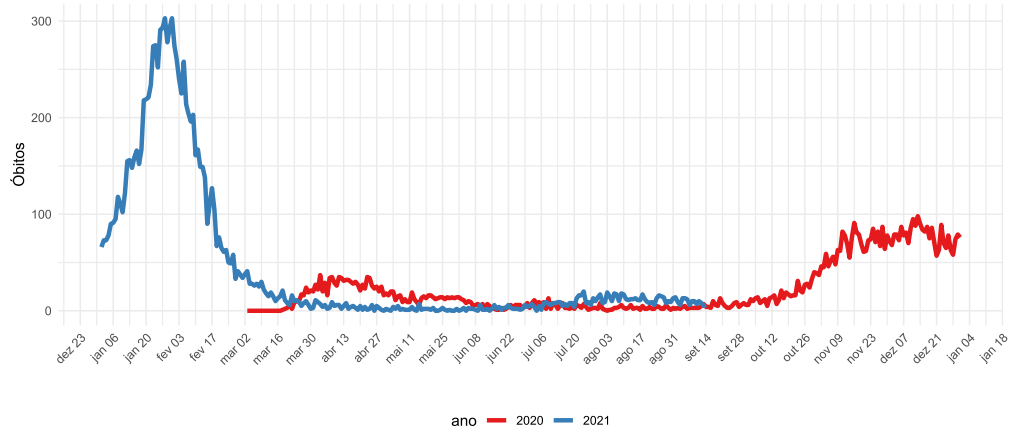
EVOLUÇÃO DA COVID-19 EM PORTUGAL







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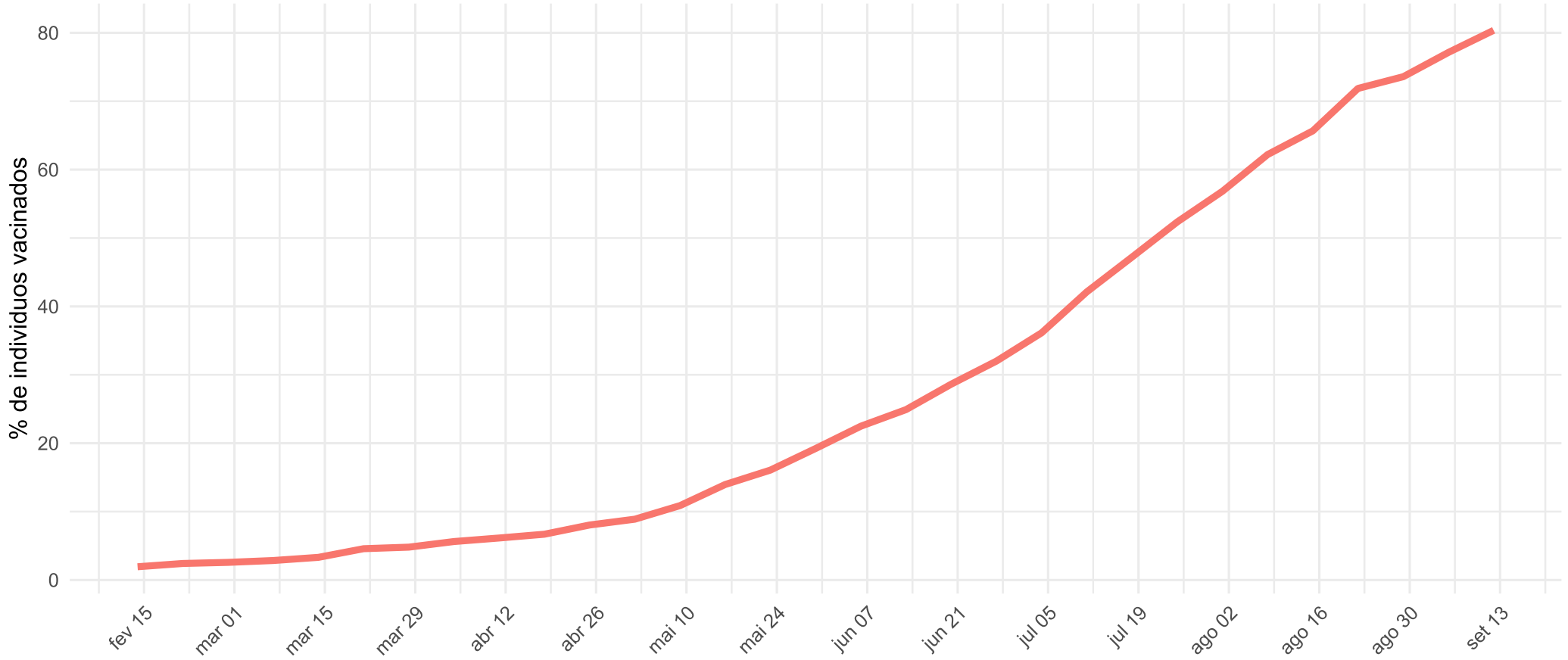
EVOLUÇÃO DA VACINAÇÃO



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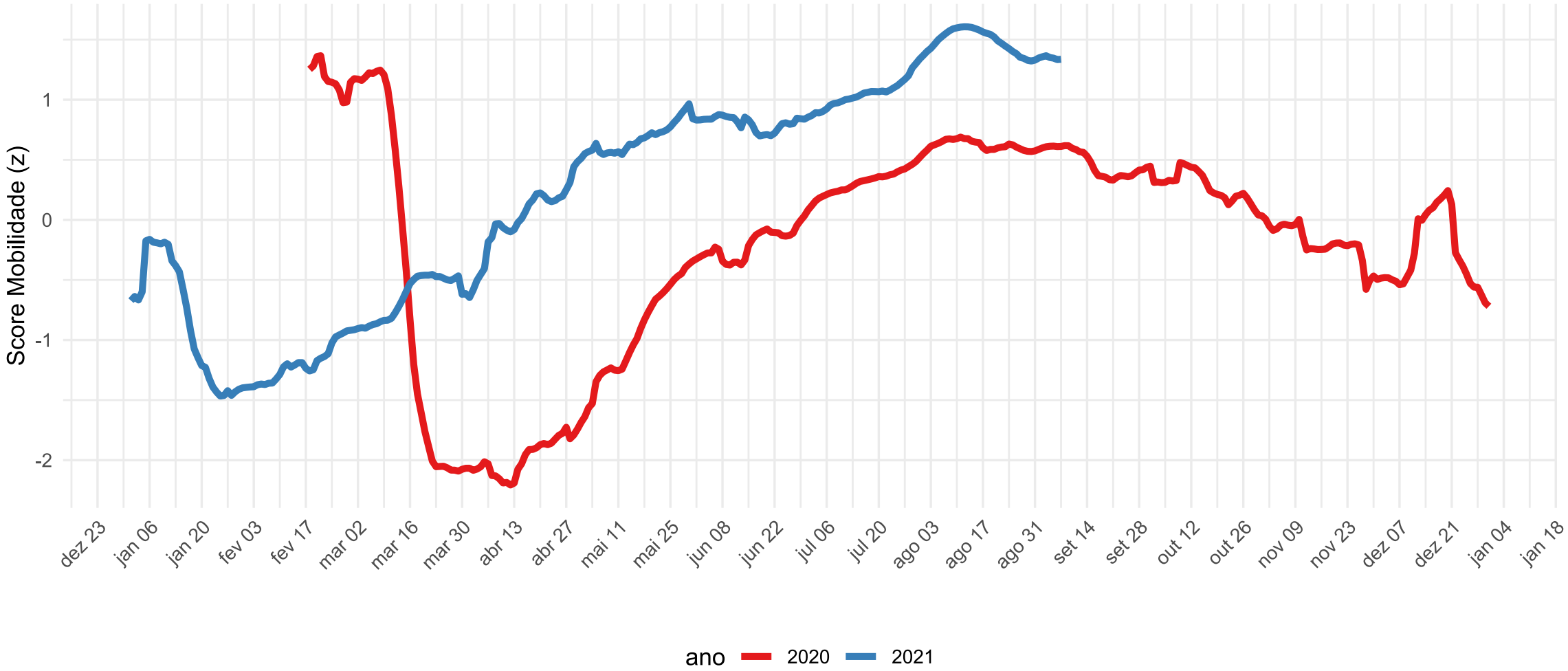
EVOLUÇÃO DA MOBILIDADE



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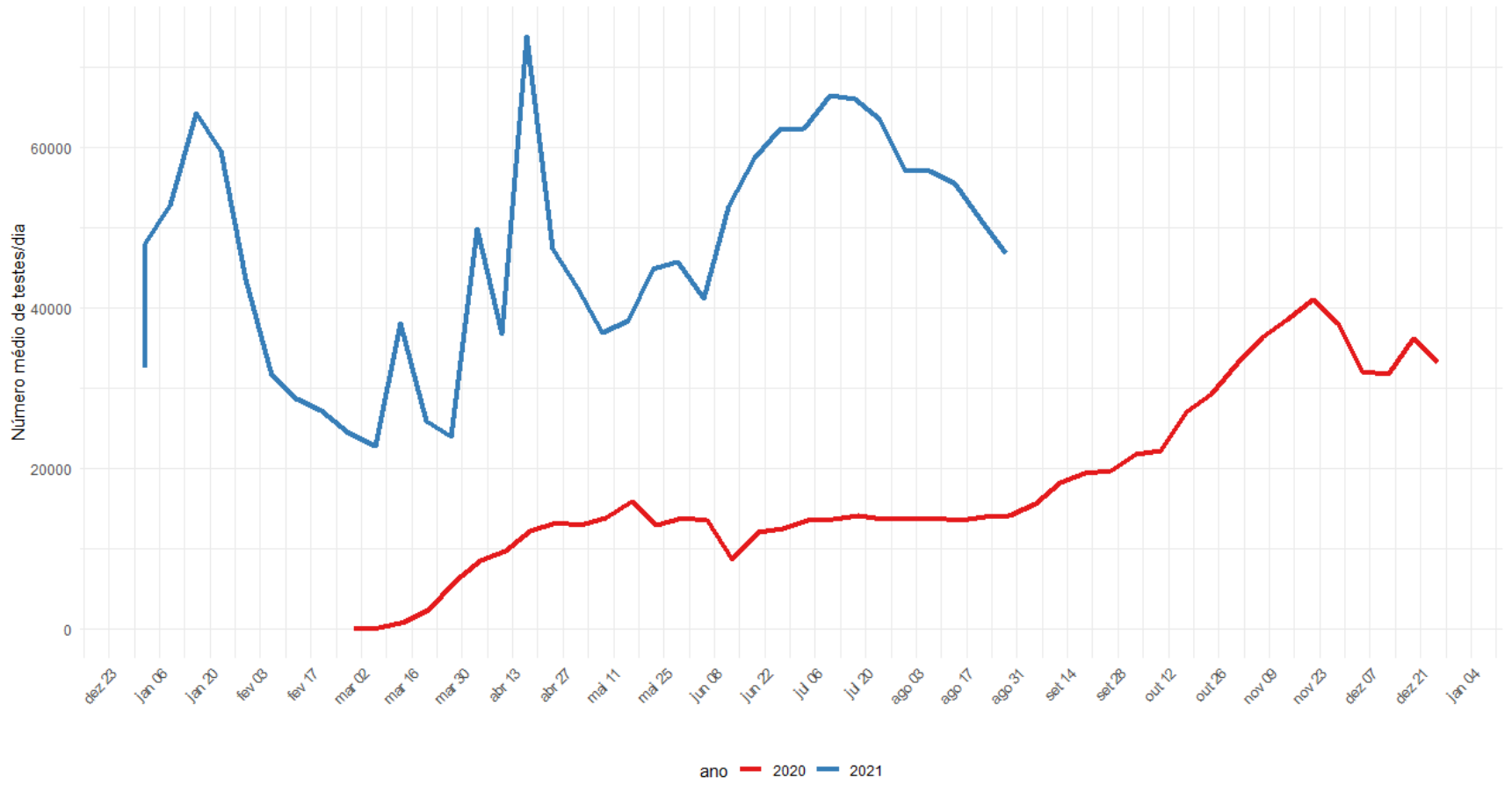
SITUAÇÃO EPIDEMIOLÓGICA EM PORTUGAL

EVOLUÇÃO DA REALIZAÇÃO DE TESTES (RT-PCR e TRAg)



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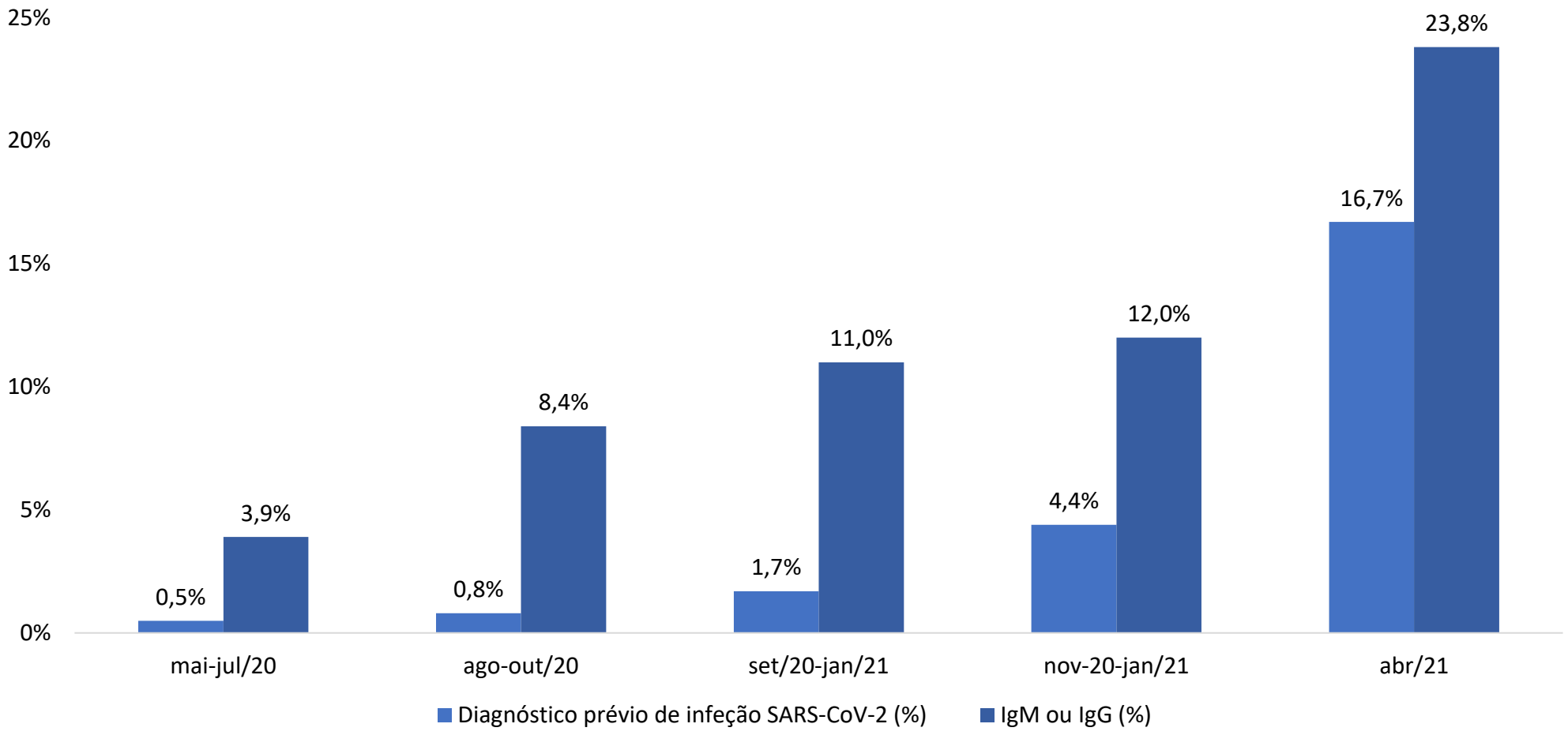
SITUAÇÃO EPIDEMIOLÓGICA EM PORTUGAL

ESTUDO SEROLÓGICO EM AMOSTRAS DA REGIÃO NORTE



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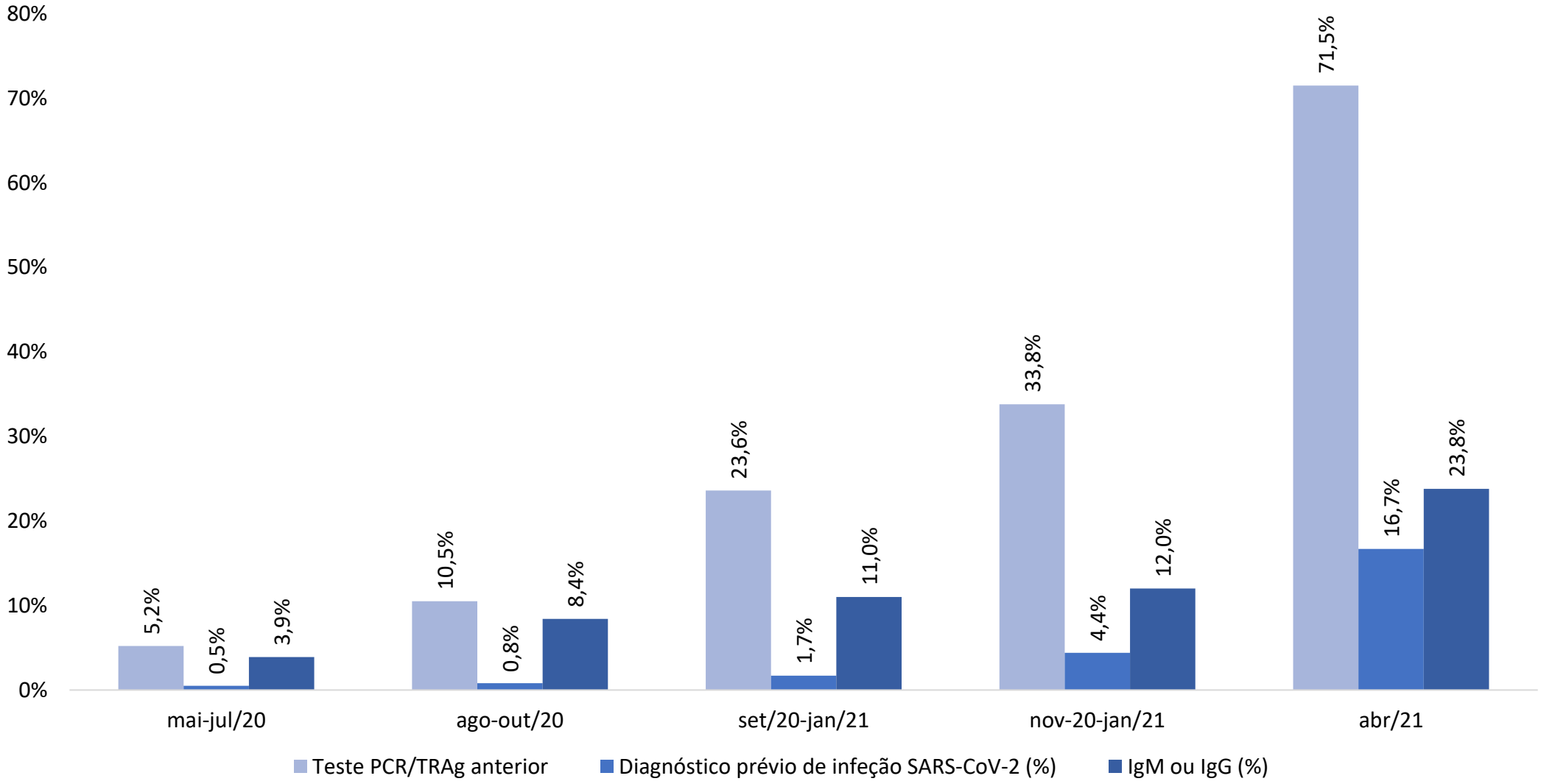


UTILIDADE DA SEROLOGIA NA INFEÇÃO POR SARS-CoV-2

- Extensão da infeção (incidência cumulativa)
- Fração não diagnosticada
- Fração assintomática ou subclínica
- Fatores de risco para a infeção
- Letalidade
- Dinâmica da resposta humoral (cinética de anticorpos)

DESEMPENHO DOS TESTES TRAg

Fabricante	Nome comercial	Sensibilidade %	Especificidade %
Abbott Rapid Diagnostics	Panbio COVID-19 Ag Test – Nasopharyngeal	85,5-86,8	99,9-100,0%
Abbott Rapid Diagnostics	Panbio COVID-19 Ag Test – Nasal	86,4-90,9	99,2%
SD Biosensor, Inc.	STANDARD Q COVID-19 Ag Test – Nasopharyngeal	73,2-89,0	87,6-99,7%
SD Biosensor, Inc.	STANDARD Q COVID-19 Ag Test – Nasal	80,5-84,6%	99,3%
Innova Medical Group	Innova Lateral Flow	48,9%	99,9%
Roche	Roche SD Biosensor	72,5-84,9%	99,4-99,5%

FIND Evaluation of Abbott Panbio COVID-19 Ag Rapid Test Device External Report Version 2.1, 10 December 2020. Accessed from: https://www.finddx.org/wpcontent/uploads/2020/12/Panbio_Ag-Public-Report_v2.1.pdf [Access date: 13.05.2021]. 2020;
FIND evaluation of SARS-CoV-2 antigen (Ag) detecting tests. Accessed from: https://www.finddx.org/sarscov2-eval-antigen/ [Access date: 13.05.2021] 2021;
FIND Evaluation of Abbott Panbio COVID-19 Ag Rapid Test Device (NASAL) External Report Version 1.0, 11 February 2021. Accessed from: https://www.finddx.org/wpcontent/uploads/2021/02/Panbio_Nasal_Ag-Public-Report_20210211v1.pdf [Access date: 13.05.2021]. 2021.
FIND Evaluation of SD Biosensor, Inc. STANDARD Q COVID-19 Ag Test External Report Version 2.1, 10 December 2020. Accessed from: https://www.finddx.org/wpcontent/uploads/2020/12/SDQ-Ag-Public-Report_20201210-v2-1.pdf [Access date: 13.05.2021]. 2020.
FIND Evaluation of SD Biosensor, Inc. STANDARD Q COVID-19 Ag Test, nasal swab External Report Version 2.0, 12 April 2021. Accessed from: https://www.finddx.org/wpcontent/uploads/2021/04/SDQ_Nasal_Ag-Public-Report_20210412_v2.pdf [Access date: 13.05.2021]. 2021;
García-Fiñana M, Hughes D, Cheyne C, Burnside G, Buchan I, Semple C. Innova Lateral Flow SARS-CoV-2 Antigen test accuracy in Liverpool Pilot: Preliminary Data. University of Liverpool; 2020;
Igloi Z, Velzing J, van Beek J, van de Vijver D, Aron G, Ensing R, et al. Clinical Evaluation of Roche SD Biosensor Rapid Antigen Test for SARS-CoV-2 in Municipal Health Service Testing Site, the Netherlands. Emerging infectious diseases. 2021;27(5):1323-9;
Salvagno GL, Gianfilippi G, Bragantini D, Henry BM, Lippi G. Clinical assessment of the Roche SARS-CoV-2 rapid antigen test. Diagnosis. 2021.

Michael Mina, adapted from Peto et al. COVID-19: Rapid Antigen detection for SARS-CoV-2 by lateral flow assay: a national systematic evaluation for mass-testing.

"AM I CURRENTLY INFECTIOUS"

SUMMARY OF 7 RAPID ANTIGEN TEST SENSITIVITIES BY Viral Load / Whether Likely Infectious

Test Sensitivity

Viral load	N samples tested per test	Innova	Abbott	Orient gene	Deepblue	Fortress	Roche SD Bio	Sure screen	Total tests performed	Avg across All tests
		Different tests							Average across all 7 rapid antigen tests	
>10 million	3	100%	100%	100%	100%	100%	100%	100%	n = 21	**100%**
1-10 million	25-28	100%	100%	100%	100%	100%	100%	100%	n = 191	**100%**
100,000 – 1 million	31-35	94%	94%	91%	91%	89%	97.1%	97%	n = 241	**94%**
10,000-100,000	34-37	68%	67%	70%	62%	76%	52.7%	43%	n = 255	**63%**
1,000-10,000	41- 42	29%	31%	12%	10%	36%	16.7%	0%	n = 293	**19%**
100-1,000	37-41	3%	2%	0%	0%	5%	0.0%	2%	n = 282	**2%**
<100	5	0%	0%	0%	0%	0.0%	0.0%	0%	n = 35	**0%**
SUMMARY OF TEST SENSITIVITIES by VIRAL LOAD (i.e. TRANSMISSIBILITY STATUS)										
Any Viral Load	176-191	54%	53%	48%	46%	55%	47%	42%	n = 1318	49%
Likely Infectious Viral Loads	**59-66**	**97%**	**97%**	**96%**	**96%**	**94%**	**99%**	**99%**	**n = 453**	**97%**

Likely Infectious
(>100,000 RNA cp/ml)

Not likely infectious
<100,000 RNA cp/ml

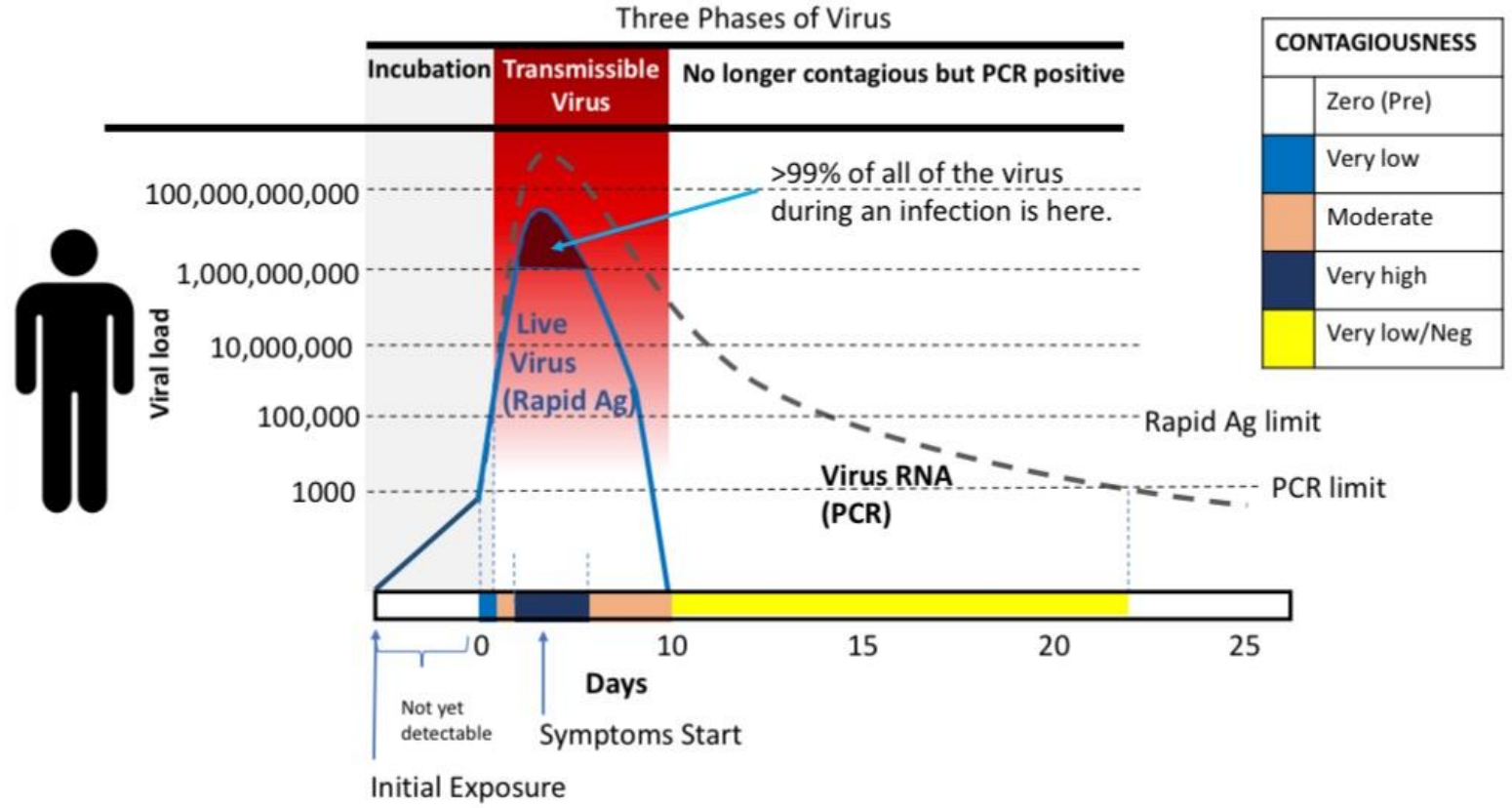
Medical Sensitivity: detect any PCR positive even if not infectious)

****Public Health Sensitivity****
Detect if currently infectious

Specificity

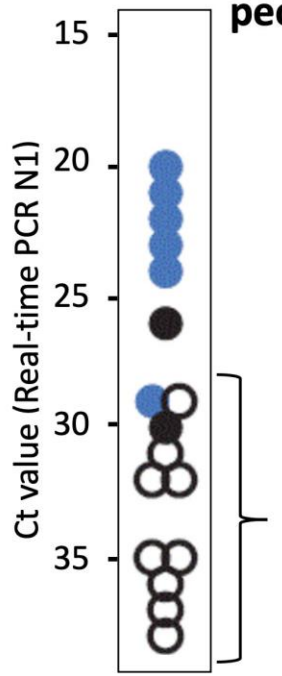
RAPID Ag TEST SPECIFICITIES (Rate of False Positives)										
Specificity (False Positive Rate)	940-1589	100.0% (0.000)	99.7% (0.003)	100.0% (0.000)	100.0% (0.000)	99.9% (0.001)	99.9% (0.001)	99.9% (0.001)	n = 7,533	99.9% (0.001)

Rapid tests have unique ability to detect contagious virus



Michael Mina, MD, PhD, Harvard T.H. Chan School of Public Health/Medical School

Rapid Antigen tests detected 100% of PCR Positive Asymptomatic people with culturable virus

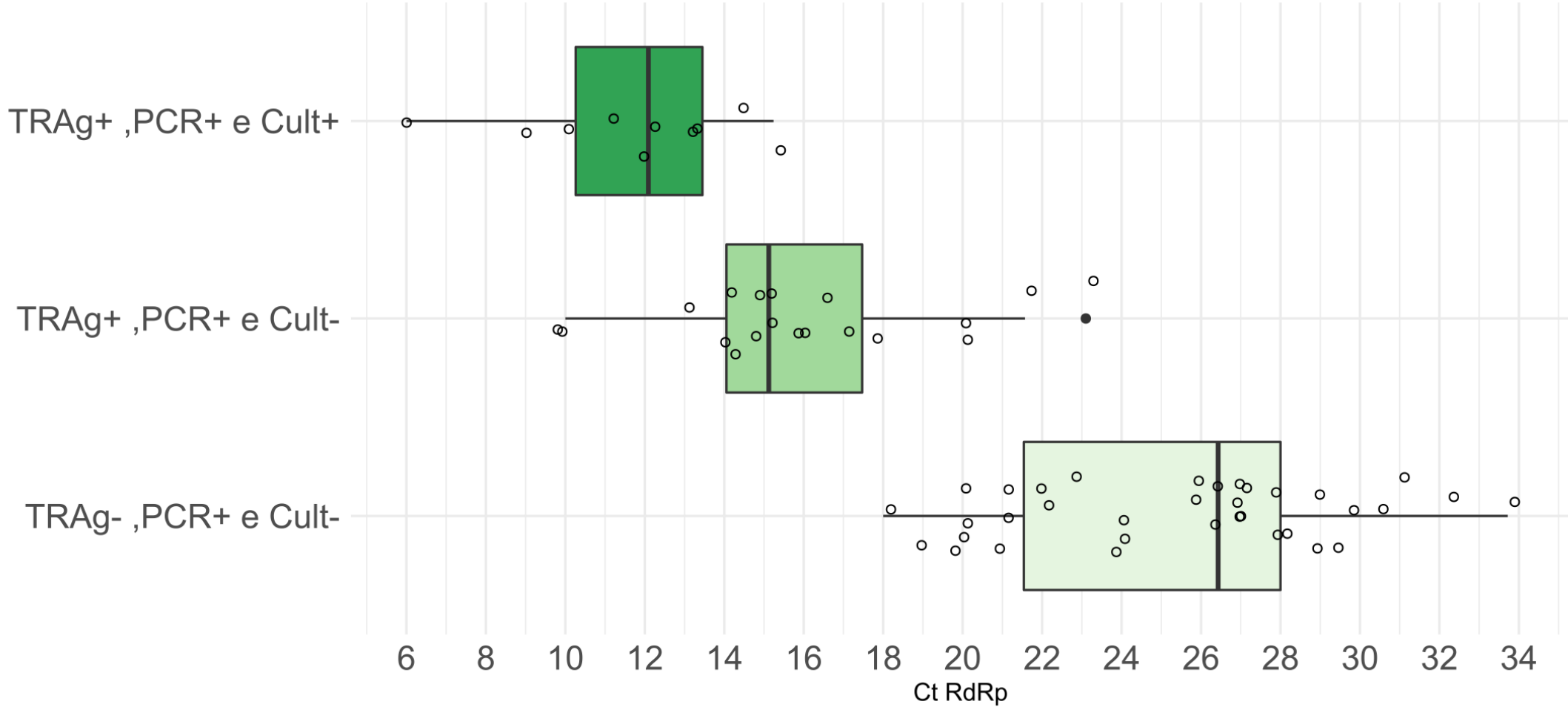


Asymptomatic PCR (+) &
- Rapid Ag Test (+), Culture (+)
- Rapid Ag Test (+), Culture (–)
- Rapid Ag Test (–), Culture (–)

These (◯) are the missed PCR (+) samples
- **0% culturable**
- **0% likely to be contagious**
- **ALL** w PCR RNA levels
  99.99% - 99.99999% LESS THAN peak viral loads in the study

Adapted by Michael Mina from Pray et al. CDC MMRWR. Jan 1 2021
https://www.cdc.gov/mmwr/volumes/69/wr/mm695152a3.htm

Tavares M, et al. From SARS-CoV-2 infection to COVID-19. A study of viral kinetics and immune response to understand contagion and clinical evolution. (FCT "RESEARCH 4 COVID-19", project number 617_613735895)



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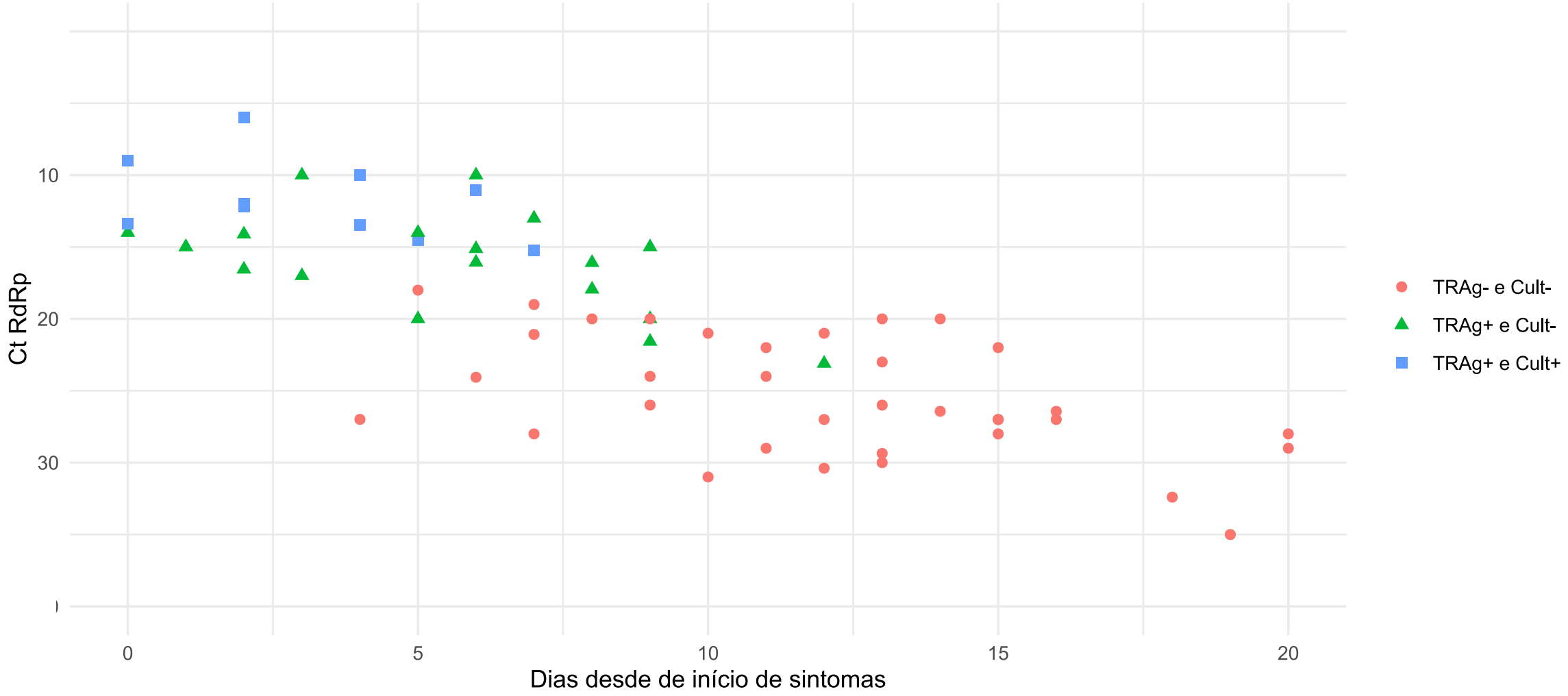
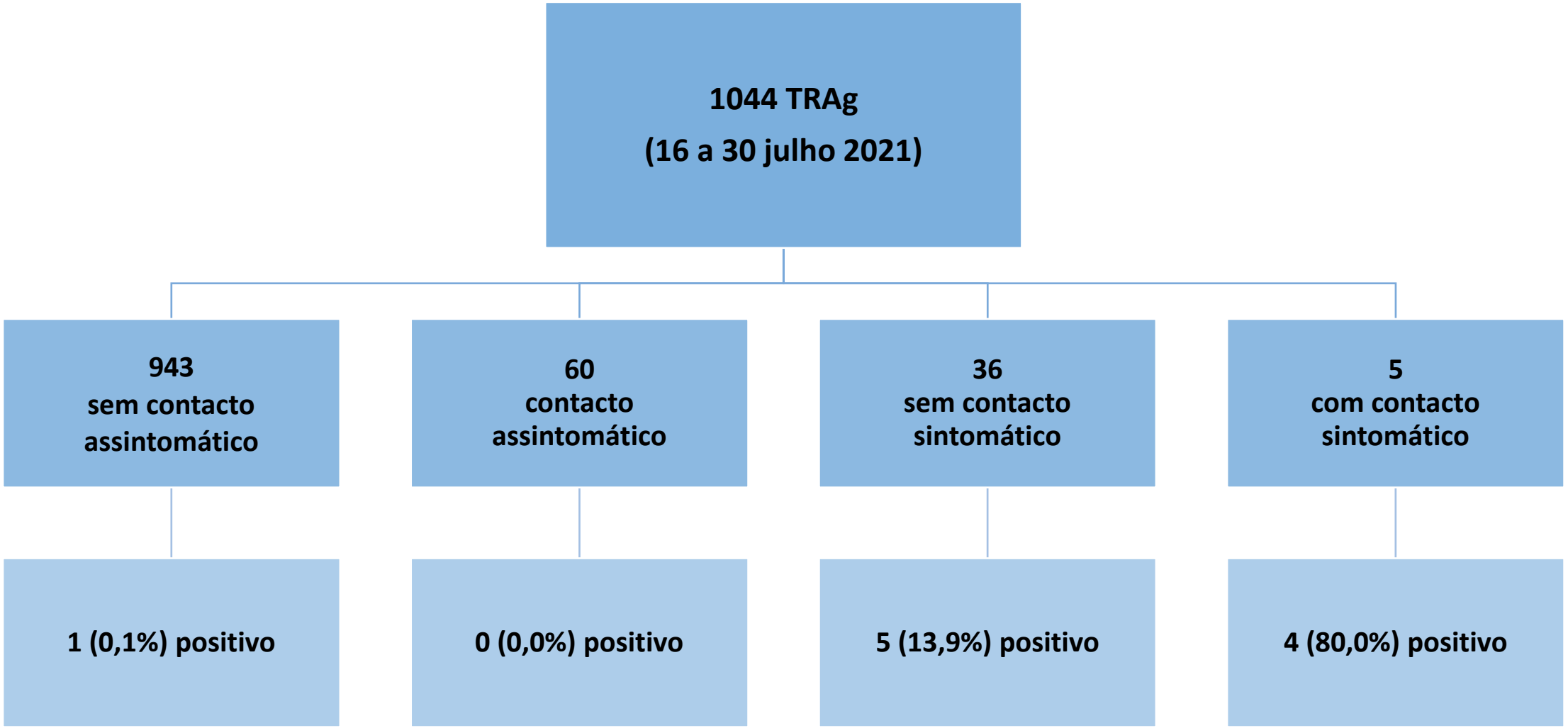


TRAg NUMA AMOSTRA DA U.PORTO



TRAg - CARACTERÍSTICAS

- Mais rápidos (<30 minutos)
- Mais baratos
- Elevada especificidade
- Menor sensibilidade, mas:
  - Calculada tendo o RT-PCR como referência (subestimada)
  - Em pessoas sintomáticas e com Ct mais baixos, a sensibilidade aproxima-se do RT-PCR

Como avaliar a imunidade no atual contexto? Qual o papel dos testes serológicos?

Necessitamos inquéritos serológicos extensos, representativos e continuados; Necessitamos vigiar o declínio da imunidade; Necessitamos explicar situações clínicas de possíveis falsos-positivos ou falsos-negativos por PCR ou TRAg.

Como identificar pessoas com alta probabilidade de transmitir a infeção?

Os TRAg são a escolha ideal.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