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BACKGROUND

- Accurate and reliable serological assays are essential for epidemiological surveillance of SARS-CoV-2.
- There is evidence of varying performance of SARS-CoV-2 assays regardless of format.
- We compare the performance of assays used in a national serosurvey undertaken in South Africa before widescale vaccination roll out with the aim of informing future surveillance activities.

METHODS

- A national representative sample of South Africans ≥12years were recruited into a national SARS-CoV-2 household serosurvey from April - June 2021
- Venous blood samples were collected and tested for SARS CoV-2 antibodies with
 - the Abbott nucleocapsid (NC)-based Architect anti-SARS CoV-2 chemiluminescent microparticle immunoassay (CMIA),
 - the Euroimmun Spike (S)-based assay
 - the Roche NC-based Elecsys Anti-SARS-CoV-2 electrochemiluminescence immunoassay (ECLIA) on the Cobas e411
- We compared antibody detection proportions

RESULTS

- 8146/9623 (84.6%) participants (median age 40 years, IQR 26-55) gave a blood sample
- 5.6% of those who gave a blood sample of reported ≥1 SARS-CoV-2 symptom in the preceding 3 months

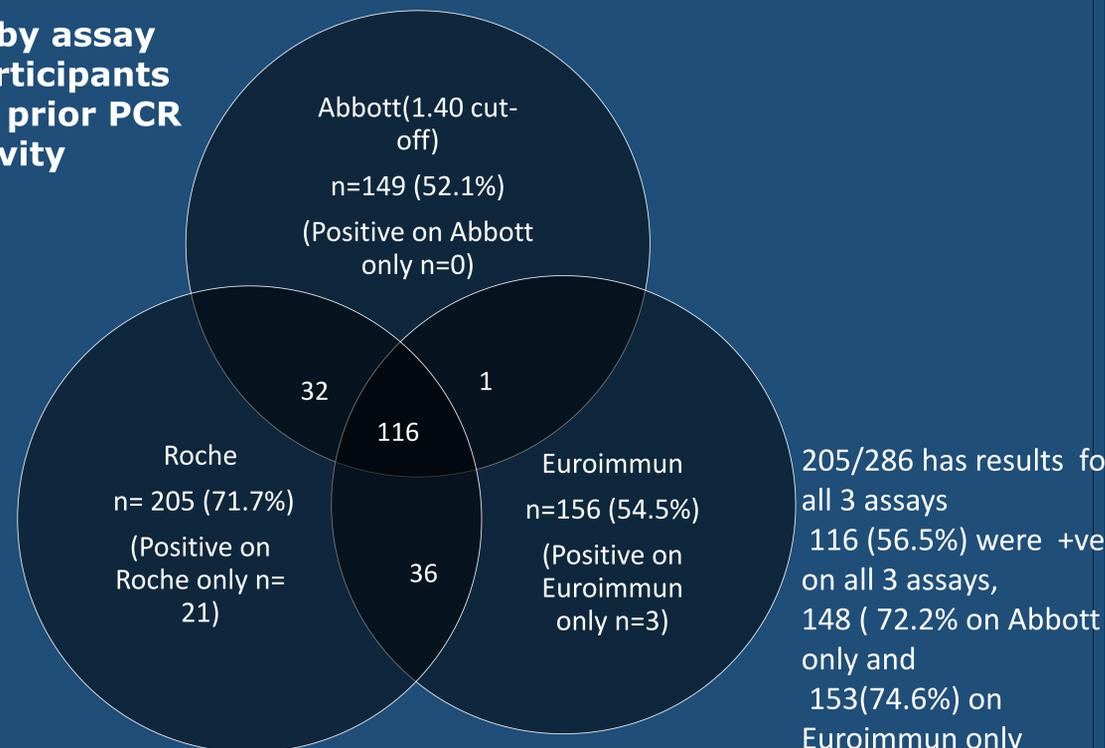
Table:-Sample positivity by assay: Sars- cov-2 household serosurvey , South Africa 2021

Assay	Method	Antibody	Antigen	Cut-Off	Tested n	Positive (%)
Abbott ARCHITECT SARS-CoV-2 IgG	CMIA (Chemiluminescent Microplate)	IgG	*NC	≥1.40	7816	1213 (15.5)
Abbott ARCHITECT SARS-CoV-2 IgG	CMIA (Chemiluminescent Microplate)	IgG	*NC	0.40	7816	2094 (26.8)
Euroimmun Anti SARS-CoV 2 (S)	ELISA	IgG	**S	0.8-1.1	7755	1677 (21.6)
Roche Elecsys Anti-SARS-CoV-2	ECLIA (Electrochemiluminescence immunoassay)	IgG Total	*NC	≥1.0	7813	3050 (39.0)

*Nucleocapsid **Spike

Of the 3050 samples +ve on Roche, 2997 had results for all 3 assays-813(27.1%) were positive all 3 assays, 1144(38.2%) on Abbott only , and 1592(53.1%) on Euroimmun only

Positivity by assay among participants reporting prior PCR test positivity (N=286)



CONCLUSIONS

- These samples collected before widescale vaccination roll out in South Africa show variable performance of these assays
- The Roche assay detected more infections than both the Abbott & the Euroimmun assays.
- Abbott and Euroimmun missed about a quarter of survey participants with prior PCR positivity and up to 62% and 47% respectively overall
- This probably reflects seroreversion previously reported with Abbott and Euroimmun and the greater sensitivity of Roche assay
- The impact of seroreversion is possibly heightened in mild infections
- Use of direct, double antigen-sandwich-based assays that are stable and have increased sensitivity over time are optimal for accurate surveillance of both natural and vaccine-induced immunity in serosurveys.
- Our current survey includes the Roche Elecsys®Anti-SARS-CoV-2 (CLIA,Total Antibody Test) to detect the NC and S proteins and the Vitros Immunodiagnostic Products Anti-SARS CoV-2 Total Reagent pack (Ortho Clinical Diagnostic Inc., United States) to detect the S protein.

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