

## Serological Testing

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## Monitoring Immune Response Against SARS-CoV-2 using Dried Blood Spot

### Introduction

Global epidemic caused by SARS-CoV-2 virus has raised a need for serological testing to detect SARS-CoV-2 specific antibodies. IgG antibodies are

formed on average 14 days after exposure and remain detectable for some time after the virus has been defeated and therefore the presence of antibodies against SARS-CoV-2 indicates a past exposure to the virus. Serological testing can be used as a convenient tool e.g. in epidemiological studies to understand and monitor the progression of epidemic in populations. Antibody testing can also be utilized to understand how the formation of IgG antibodies are linked to protective immunity, how long antibodies persist in the body and for use in large-scale surveys. For the vaccine development serological testing can be used in clinical trials to monitor vaccine response and IgG formation over time. After vaccination programs have been implemented, serological surveys may be of interest to monitor the longevity of IgG antibodies.

## Dried Blood Spot Sample (DBS) in Population Screening

Dried Blood Spot is a sample type where only few drops of blood are collected e.g by fingerprick and dried directly on a filter paper card. This minimally invasive blood sample collection method is more acceptable to patients than venous puncture that is needed for typical assays measuring the analyte from serum or plasma, therefore, it has the potential for sampling even in non-clinical settings such as the home. The sample card can be easily shipped via regular mail and overcomes logistical barriers for sample collection as no cold transport or sample processing is needed. Since large numbers of samples can be obtained in short time periods, several samples can be analyzed from one sample card and while keeping cost to a minimum, it offers an ideal method for population based testing. Dried blood spot sample is a proven population-based screening method that has been used successfully in newborn screening for decades. A recent study of University of Milan showed a good concordance between results obtained with DBS eluates and serum samples (Amendola et al. 2020).

### Aim

The aim of our project in Milan is to evaluate the prevalence of SARS-CoV-2 in the Milanese school children population. In order to choose the method to be used we compared two commercially available assays that detect SARS-CoV-2 IgG antibodies from dried blood spot samples. The selected assay will be used for screening of school children in Northern Italy to understand how widely the virus has penetrated within this population.

### Methods

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### Results

PerkinElmer and Euroimmun results were well in concordance (Figure 1.). 14 samples out of 65 were classified with Euroimmun assay as positive, and 13 of them were classified also with PerkinElmer assay as positive. For one sample the classification was in disagreement but the sample quality was found to be unsatisfactory. In addition, one sample gave a borderline result with Euroimmun assay.

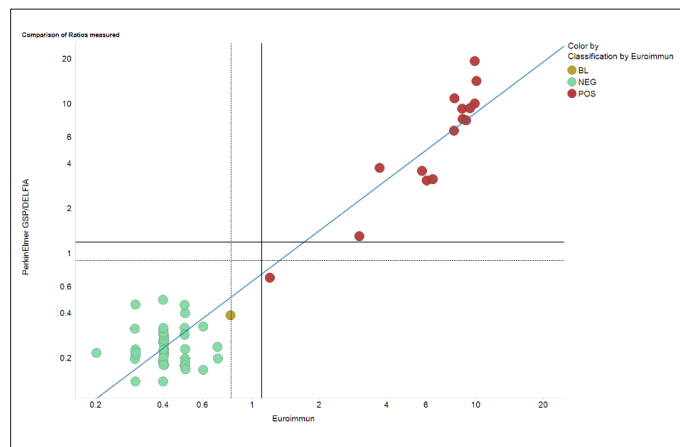


Figure 1. DBS results Euroimmun results plotted against PerkinElmer results. Positive cut-off for ratio (EI: 1.1 and PE: 1.2) is shown as solid line and borderline cut-off for ratio (EI: 0.8 and PE: 0.9) as dashed line.

## Conclusions

GSP/DELIA Anti-SARS-CoV-2 IgG assay is a fully automated high-throughput solution from sample to result which enables large population screening using dried blood spot samples in a straightforward manner. The assay is robust, and especially in a newborn screening laboratory, easy to use which is crucial when testing large sample volumes. The device variation at cut-off area may cause borderline cases result as test negative or negative as borderline. Although the true positivity or negativity of the tested DBS samples was unknown, the good correlation to Euroimmun assay indicates the GSP/ DELIA Anti-SARS-CoV-2 IgG assay performance is well applicable for SARS-CoV-2 IgG screening.

## References

1. Dried Blood Spot as an Alternative to Plasma/Serum for SARS-CoV-2 IgG Detection, an Opportunity to Be Sized to Facilitate COVID-19 Surveillance Among Schoolchildren. Amendola A, Bianchi S, Gori M, Barcellini L, Colzani D, Canuti M, Giacometti V, Fabiano V, Folgori L, Zuccotti GV, Tanzi E. *Pediatr Infect Dis J.* 2020 Nov 10.

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