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ORIGINAL RESEARCH

A Multiplex Bead Serology Panel For Vaccine-Preventable Diseases Using Dried Blood Spots

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Background: Vaccines are effective tools to improve public health. The effectiveness of vaccines is, however, dependent on the overall level of protection in a population. Antibodies to vaccine-related antigens are good biomarkers of protection and serosurveillance can help target vaccination programs. An integrated approach to perform serosurveillance on multiple vaccine-preventable diseases (VPDs) has been advocated and would be facilitated by a standardized multiplex immunoassay. In this report, we describe the evaluation of the performance of a multi-lyte bead-based serology panel for 12 VPDs which uses a dried blood spot sample from a finger prick (*ImmunoProfile Antibody Test System*).

Methods: Verification/validation studies were performed at a CLIA-certified clinical laboratory (BioAgilytix Labs, Boston, MA) on blood collected from dried blood spot (DBS) card samples from adults and children. In addition, proof-of-principle pilot serosurveillance studies were performed to demonstrate the potential of this test to identify protection gaps in adult and pediatric populations.

Results: This study demonstrates that the ImmunoProfile Antibody Test System has the requisite analytical performance to be a reliable tool for determining levels of protection to VPDs. The pilot serosurveillance studies demonstrate that this test reveals gaps in protection comparable to what has been shown using immunoassays for individual antibodies using serum samples.

Conclusion: Serological survey data obtained with the validated ImmunoProfile Antibody Test System could provide a wealth of information on levels of protection and could unearth vaccination gaps that may not have been anticipated.

Keywords: antibody, serology, vaccine-preventable disease, protective levels

Introduction

Vaccines are an important medical and public health tool to reduce morbidity and mortality caused by infectious diseases. Recent and ongoing improvements in vaccine development have increased the efficacy of vaccines. Also, guidelines on the utilization of vaccines have recommended more frequent vaccination for certain diseases such as tetanus and pertussis and universal vaccination for several diseases, such as influenza and hepatitis B viruses. In addition, the recent SARS-CoV-2 pandemic has spurred new interest by the pharmaceutical industry in developing new vaccines including the new respiratory syncytial virus vaccine. Despite these developments, there remain many challenges with efforts to increase the prevalence of protection to infectious diseases using vaccination. Vaccination rates often fall short of public health officials' goals especially goals to achieve the herd immunity threshold.[1] Furthermore, misinformation about the side effects of vaccines and vaccine hesitancy have hampered efforts to promote widespread vaccination. Finally, the high prevalence of individuals who are immunocompromised and/or have a chronic disease, can reduce the immune response to vaccines. These issues and others have contributed to the high prevalence of gaps in protection to vaccine-preventable diseases among certain populations.[2,3]

Population surveillance is an important public health activity including efforts to assess the level of protection to vaccine-preventable diseases (VPDs) to better target vaccination programs.[4–7] Antibodies serve as biomarkers of protection to VPDs and measuring antibody levels can be used to identify vaccination gaps, inadequate vaccine

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responses, or waning immunity. Individual tests for antibody levels are commercially available for measles, mumps, rubella, herpes zoster, tetanus, pertussis, diphtheria, etc. Each of these antibody tests is useful to assess the prevalence of protection to a single infectious disease. Small serosurveillance studies to determine the immune status of a population against multiple infectious diseases have shown the value of testing for multiple VPD antibodies.[1,8] Using single-analyte tests in large studies, however, would be inefficient and cost-prohibitive. In fact, an integrated approach has been advocated to be a better way to carryout serosurveillance for VPDs.[9]

A number of multiplex bead assays (MBA) have been developed for the simultaneous determination of serum antibodies to infectious agents to enhance serosurveillance efforts.[10–12] Also, several reference laboratories offer MBA tests for measles, mumps, rubella and varicella zoster virus antibodies. Use of MBA has enabled population-based surveys that can characterize multi-pathogen immunologic profiles on a given population. Most of these MBAs, however, have been applied to infectious disease surveillance, particularly, neglected tropical diseases.[13] There have been a number of studies, however, that support the use of MBA in serosurveys that assess population immunity to several infectious agents simultaneously.[10,14,15]

It has been proposed that a current limitation of bead-based multiplex technologies such as Luminex, is that most disease-specific antigen-coupled beads are not commercially available and that commercial development of these reagents would enable better standardization across laboratories.[9] In this report, a commercially available MBA for antibody levels to 12 VPDs is described (*ImmunoProfile Antibody Test System*). This antibody test panel has potential value for public health studies to assess overall gaps in protection in a population. This test also can be used by individuals wanting to know their own gaps in protection to inform their vaccination needs. In addition, this test can help health care professionals (HCP) with their vaccination-status credentialing requirements.

The *ImmunoProfile Antibody Test System*, in contrast to most other serological tests for VPDs, is performed on blood collected from a finger prick which is then dried on a dried blood spot (DBS) card rather than serum from a phlebotomy. Also, since the test measures a panel of antibodies simultaneously, it is important to compare results obtained from the *ImmunoProfile Antibody Test System* to the comparable individual antibody immunoassays. To address this issue, verification and analytical validation studies were performed and the results are shown below. We also describe proof-of-principle pilot studies that demonstrate the potential of this test to identify protection gaps in adult and pediatric populations.

Materials and Methods

Test Description

ImmunoProfile Antibody Test System. The ImmunoProfile Antibody Test System is a semi-quantitative multiplex serological test for the detection of the level of immunoglobulin G (IgG) antibodies specific to a panel of antigens associated with 12 infectious disease agents for which vaccines are available. The vaccine-preventable diseases (VPD) are measles, mumps, rubella, polio (serotypes 1, 2, and 3), hepatitis A virus, hepatitis B virus, varicella-zoster virus (chicken pox), tetanus, diphtheria, Bordetella pertussis (whooping cough), Covid-19 (SARS-CoV-2), and Hemophilus influenza type B. The test sample is a blood sample collected by finger prick and collected on a DBS card.

The ImmunoProfile Antibody Test System is available commercially for both adults and children (ages 4+ years old) in all 50 US states and Washington, D.C. as a laboratory-developed test (LDT) performed at BioAgilytix Laboratory (Boston, MA, USA), a CLIA/CAP-approved (Clinical Laboratory Improvement Amendments/College of American Pathologists) facility. The ImmunoProfile Antibody Test System has not been submitted or authorized for use by the FDA under the emergency use authorization (EUA) guidelines related to SARS-CoV-2 testing in the US and when used commercially no results are reported for SARS-CoV-2 except when used for research-use-only (RUO).

Samples

All research studies on human samples were performed in accordance with the principles stated in the Declaration of Helsinki. De-identified serum samples from 334 adults were purchased from ZEUS Scientific (Branchburg, NJ USA) in March 2021 from a serum bank of samples collected over the previous 5 years (2016–2021). All of these samples were obtained under a collection protocol reviewed by the IRB at Zeus Scientific. The donors were all US residents, ages 18 or greater of both genders, but numbers of males and females was not available. These serum samples were used in the preliminary study, the results of which are shown in Table 1.

Table 1 Gaps in Protection to 11 VPDs in 334 healthy Adults

VPD	[a]Number Above AbU 120 (%)	Number Below AbU 120 (%)
Hepatitis A	73 (22)	261 (78)
Hepatitis B	15 (5)	319 (96)
Diphtheria	296 (89)	38 (11)
Pertussis	264 (79)	70 (21)
Tetanus	318 (95)	16 (5)
Polio (type 1, 2, 3)	309 (92)	25 (8)
H. influenza type b	285 (85)	49 (15)
Measles	304 (91)	30 (9)
Mumps	329 (99)	5 (2)
Rubella	315 (94)	19 (6)
Varicella	329 (99)	5 (2)
All 11 VPD	3 (1)	331 (99)

Notes: [a]120 AbU is the threshold for qualitative level of protection.

Serum and DBS samples were prospectively collected from 87 healthy adults (≥18 years old). These 87 samples were used in the validation studies and predicate comparison studies (Table 2).

Serum and DBS samples were collected in 2024 from 100 children (ages 4–17) with informed parental consent reviewed by the Institutional Review Board (IRB) at Precision for Medicine (Bethesda, MD USA). These samples were used to collect the data shown in Tables 3 and 4.

Table 2 Comparison of the ImmunoProfile Antibody Test System With ELISA Immunoassays for Each of the Listed VPDs

VPD	Predicate Assay	Number of Tests	Total Percent Agreement	95% CI
Hepatitis A	Siemens Atellica	196	97	94–100
Hepatitis A	[a]ARUP LDT	57	96	90–100
Hepatitis B	ARUP LDT	53	96	90–100
Diphtheria	ARUP LDT	53	98	92–100
Tetanus	ARUP LDT	54	100	94–100
Pertussis	ARUP LDT	20	95	80–100
Polio	ARUP LDT	25	100	80–100
H. influenza b	[b]B-Binding assay	41	90	84–100
Measles	[c]Zeus MMRV Athena	63	95	86–100
Mumps	[c]Zeus MMRV Athena	65	96	87–100
Rubella	[c]Zeus MMRV Athena	70	100	95–100
Rubella	[d]BioPlex 2200	196	98	96–100
Varicella	[c]Zeus MMRV Athena	70	99	92–100
Varicella	[d]BioPlex 2200	196	97	94–100

Notes: [a]Associated Regional and University Pathologists, Inc. (Salt Lake City, UT) laboratory-developed test. [b]Zeus Scientific LDT. [c]ZEUS Athena Multi-Lyte MMRV IgG Plus Test System. This test is only approved for disease detection, not protective antibody level determination. [d]BioPlex 2200 (Bio-Rad Laboratories) MMRV IgG.

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Table 3 Antibody Levels for 96 Pediatric DBS Samples (Ages 4–17 Years)[a]

VPD	Vaccine	[b]ABU ≥120 (%)
Hepatitis A	HAV	97
Hepatitis B	HBsAg	72
Diphtheria	DPT	100
Pertussis	DPT	98
Tetanus	DPT	93
Polio	Polio	100
H. influenza B	HIB	100
Measles	MMR	78
Mumps	MMR	100
Rubella	MMR	100
Varicella	Varicella	100

Notes: [a]100 samples were tested and 4 gave invalid results for one or more targets. Ninety-six percent of the children had received the full vaccination protocol for all 11 vaccines. [b]AbU = antibody units. The threshold for protection is 120 units.

Table 4 Results of a Prospective Study Showing the Prevalence of Protection to All 11 VPDs Among 3 Demographic Populations in the U.S

Population	Not Fully Protected (%)	[a]Fully Protected (%)
[b]Pediatric	40	60
[c]Adults	86	14
[d]Migrants	67	33

Notes: [a]AbU above the threshold for protection (120 AbU) for all 11 VPDs. [b]Ninety-six samples from children shown on Table 3. [c]DBS samples from sixty-four adults who ordered the ImmunoProfile Antibody Test System online. [d]DBS samples collected from 51 asylum-seekers in a NYC shelter (47 gave valid results).

For the prospective pilot studies dried blood spot samples from 64 adults (ages 26–79; 36% female, 64% male) who ordered the test online and 51 migrants (ages 21–57) were collected in 2024 using the ImmunoProfile Blood Spot Card Kit (part #8375) as instructed within the associated product insert. DBS samples from the adult migrants at the New York City shelter were obtained with informed consent which was reviewed by the IRB at ParCare Health Network (Brooklyn, NY USA). The 64 adult DBS samples were obtained under informed consent. The adult samples, as well as the pediatric DBS samples, were used in the pilot studies, the results of which are shown in Table 4.

After collection, dried blood spots were stored at room temperature for up to 7 days prior to testing. Specimen collection was carried out in accordance with NCCLS document M29: Protection of Laboratory Workers from Infectious Disease.[16]

Assay Procedure

The ImmunoProfile Antibody Test System was performed according to the associated product insert (Supplemental Data 1). Briefly, a 3 mm punch from the DBS was placed in the wells of a 96-well plate and samples were eluted with 100

microliters of phosphate buffered saline for one hour at room temperature (RT). Fifty microliters of a bead slurry containing each antigen conjugated to magnetic polystyrene beads were added to the wells of a separate plate. Fifty microliters of the eluted sample was then added to the plate containing the bead slurry. After mixing thoroughly, the plate was incubated at RT for 30 minutes. Each well washed thoroughly to remove unbound antibody. One hundred-fifty microliters of phycoerythrin-conjugated goat anti-human IgG were added and the plate incubated for 30 minutes at RT and then non-bound conjugate was washed off the plate of magnetically held beads. The plate was analyzed on a Luminex Flex Map 3D instrument which generates results for the amount of phycoerythrin (PE) fluorescent reporter present on each bead set. Each plate contains 3 positive controls and 1 negative control. The presence of intra-well calibration bead sets allows conversion of raw mean fluorescence intensity (MFI) to antibody units (AbU), a proprietary measurement unit developed to simplify reporting of results for all analytes. Antibody units (AbU) was developed to provide a standardized scaling for easy interpretation of multiple diseases simultaneously.

Determination of the Threshold for Protection

The cutoff values for protection for each of 11 VPDs (excluding COVID-19) were set using World Health Organization (WHO) standards. The WHO cut-off for protective antibody levels for each VPD is in IU/mL. We performed dilutions on each WHO standard to verify that the MFI we achieved at the cut-off of each antigen was within the linear range of the assay. Conversion of MFI to WHO IU/mL was then possible. However, because each VPD had a different IU/mL cut-off, we normalized all the cut-off values to AbU by using calibration standards. For all tests on the panel, an AbU result greater than 120 is considered a protective level. Results that are less than or equal to 120 AbU units may indicate a lack of protection.

For COVID-19, the cut-off was developed based on several COVID-19 antibody tests that received FDA emergency-use authorization (EUA). Although COVID-19 antibodies to nucleocapsid NC and the receptor-binding domain (RBD) of the S protein are included in the panel, the results can only be used for RUO studies and thus we have not included any COVID-19 results in this study.

Preliminary Studies

To determine whether our MBA test could assess gaps in protection among adults, deidentified serum samples were collected from 334 healthy US adults (age ≥18 years).

Validation Studies

The validation studies were performed at a CLIA-certified clinical laboratory (BioAgilytix Labs, Boston, MA). The study entitled, *Performance Validation Report for Semi-quantitative Detection of IgG Antibodies from DBS Cards*, and completed in May 2022 under guidelines and specifications of the College of American Pathologists (CAP) and the Clinical Laboratory Improvement Amendments (CLIA). The ImmunoProfile Antibody Test System uses the test system reagents and the Luminex Flex Map 3D instrument. Separate validation studies were performed on deidentified dried blood spot samples from healthy vaccinated adults (87 samples) and children (100 samples).

Confidence intervals in Table 2 were calculated using the Excel spreadsheet calculator.

Pilot Studies

To assess gaps in protection among adults, deidentified serum DBS samples were collected from 87 healthy US adults (age ≥18 years). To assess gaps in protection among children, deidentified DBS samples were collected from 100 healthy, vaccinated US children (ages 4–17 years). In addition, DBS samples were obtained from 51 asylum-seeking immigrants in a New York City shelter from nine countries in Central America, South America and Western Africa. Testing of all samples with the ImmunProfile Antibody Test System was performed at BioAgilytix Labs (Boston, MA, USA).

Results

To assess gaps in protection among adults, deidentified serum samples were collected from 334 healthy US adults (age ≥18 years). As shown in Table 1, of the 334 samples run, 99% had non-protective levels of antibody to one or

more of the 11 VPDs. The percentage of non-protective levels for each analyte was from 1.5 to 95.5%. Hepatitis B virus, hepatitis A virus and pertussis had the highest percentage at 95%, 78% and 21%, respectively. While these percentage may not represent the general US adult population, they are consistent with recent reports in immunization gaps in the US and around the world.[3,17,18]

A verification/validation study evaluated the performance of the ImmunoProfile Antibody Test System with regard to a number of parameters including limit-of-detection (LoD), interference, cross-reactivity, precision (intra and inter), carry-over, long-term stability, lot-to-lot concordance, predicate assay comparative studies and qualitative comparative studies between serum and DBS samples (see Supplemental Data 1).

Interference and Cross-Reactivity

Studies using bilirubin (unconjugated, cholesterol, triglycerides, and intralipids) showed no evidence of interference using low-positive and high-positive samples (data not shown). The ImmunoProfile Antibody Test System also did not exhibit intra-assay antigen/antibody cross reactivity (see Supplemental Data 1).

Intra-Assay Precision

Twenty assay replicates were performed on eight different samples. Each sample's replicates were performed within a single assay run. The mean, standard deviation, and average % CV were calculated for all 13 analytes, for each sample. The average % CV for each analyte was under 10 for all analytes except for pertussis which was an acceptable 14.65 (see Supplemental Data 1).

Inter-Assay Precision

Two operators, over three separate days, tested the same eight samples as in the intra-assay precision study. Five replicates of each sample were assayed, in six separate runs. The overall % CV for each analyte was under 20% (see Supplemental Data 1).

Inter-Laboratory Concordance

Eighty-seven DBS samples were assayed at ZEUS Scientific (Branchburg, NJ) as well as at BioAgilytix (Boston, MA), totaling 1131 assay results at each laboratory when considering all 13 analytes. Variables encompassed by this study were as follows:

i. Different lots of reagents were used at each testing site
ii. Different operators performed the assay procedures at each testing site
iii. Dried blood spot sample storage times prior to testing were different for each site
iv. Different automated washers were used at each testing site

Of the 1131 assays performed, there was agreement on 1096 samples for a total percent qualitative result agreement of 96.91% (95% CI 95.73–97.77).

Studies were also performed to compare the qualitative results of serum and DBS cards. The overall concordance was 96% using paired samples from adults and 93.2% for samples from children (see Supplemental Data 1).

The ImmunoProfile Antibody Test System was also compared against ELISA immunoassays for each of these VPDs performed independently at CLIA-certified reference laboratories. As shown in Table 2, the overall concordance of the ImmunoProfile Antibody Test System with independent CLIA-certified laboratories using traditional ELISA assays was ≥95% for all analytes except for H. Influenza B which was ≥90%.

To assess gaps in protection among children, deidentified DBS samples were collected from 100 healthy, vaccinated US children (ages 4–17 years). Vaccination histories were available for all 100 children and 97–100% of the children were fully vaccinated against each of the eleven VPDs for which antibody levels were measured. Seven of the children were only 4 years old and may not have received their final dose of MMR. Of the 100 samples, 4 gave invalid results and were not included in the analysis. Although 97% and 100% of children were fully vaccinated for measles and hepatitis

B viruses, respectively, the percentage with protective levels of antibody were only 78% and 72%, respectively (Table 3). Multiple factors could be contributing to these results including age-related waning of immunity. In fact, 70% of the samples with <120 AbU were from children 11–17 years old (data not shown).

Table 4 shows a summary of the levels of protection we observed with the ImmunoProfile Antibody Test System on pediatric, adult, and recent immigrant populations. Sixty percent of the children were fully protected whereas only 14% of the adults and 33% of the migrants were fully protected (Table 4). The level of protection ranging from 22% to 98% for the adults and was lowest for HAV (22%), measles (78%), HBV (79%), and pertussis (81%) (data not shown). For the migrants, protective levels were only 50% for measles and 44% for HBV, but were 85–100% for the other 9 VPDs (data not shown).

Discussion

This study demonstrates that the ImmunoProfile Antibody Test System has the requisite analytical performance to be a reliable tool for determining antibody-associated levels of protection to VPDs. In addition, small pilot studies on samples from adults and children show that it can uncover gaps in protection in a population.

A number of problems plague the effectiveness of vaccines as a public health strategy to ameliorate the morbidity and mortality associated with infectious diseases. First, not all vaccinated individuals exhibit a fully protective immune response to a given vaccine. This can be due to an immunocompromised state from an immunodeficiency disease, cancer, immunosuppressive drugs, advanced age, or chronic diseases. Furthermore, immunocompetent individuals may also have variable responses to vaccination and re-vaccination may be needed. Second, vaccination records are often incomplete, inaccurate, or depend on people's memories. Unfortunately, in the United States there is no national organization that maintains vaccination records. Most adults do not know their protection level to common infectious diseases. Third, rates of vaccination in a given population do not approach 100%.[2] Depending on the vaccine, the demographics of the population and cultural and religious factors can affect the percentage of individuals in any given population who get vaccinated. An additional factor is the rise in vaccine-hesitancy which can further reduce the rate of adoption of vaccination.[19] It has been proposed that testing for antibody levels to VPDs may be an effective tool to counter vaccine hesitancy especially in children since non-protective levels of antibodies may promote the decision to vaccinate.[20] Results from the test panel can also prevent unnecessary vaccination and its potential adverse effects.

According to the CDC, based on surveys, nearly 9 out of 10 Americans have gaps in immunity against common infectious diseases and most adults are not aware that they may have gaps in their immunization status.[3] This makes it difficult for public health officials, employers, HCPs, and individuals themselves, to be certain of their vaccination status and/or whether their original vaccine response has waned. In addition, certain populations are particularly susceptible to low vaccination rates and low levels of protective antibodies. A recent cross-sectional study of asylum-seekers in New York City revealed significant prevalence of non-protective levels of antibodies to multiple VPDs.[21]

Currently, testing for antibodies to individual VPDs is offered by many clinical reference laboratories, but testing for multiple antibodies is inefficient and costly using these tests. Large-scale serosurveillance studies that use individual tests would require multiple vials of blood and visits to multiple clinical laboratories and is cost-prohibitive. The total cost (including all fees, shipping and prescription costs) of the ImmunoProfile Panel Antibody Test is about $21/VPD. In contrast, the cost of obtaining an antibody level for each VPD using online services or major reference laboratories is 3–4 times higher based on publicly available information. Even public health laboratories charge 1–3 times per test and most do not offer serology for all 11 VPDs. Therefore, the ImmunoProfile Antibody Test System is a cost-effective and efficient means to provide public health officials, health care providers, employees, and individuals with an overall picture of their overall protective levels of antibody to multiple VPDs.

Results from the ImmunoProfile Antibody Test System are presented in a visual form which allows the patient and their HCP to easily see whether the level of antibodies for each VPD are in the range that is considered protective or below that range and thus, non-protective. Results include a qualitative result with numerical output for all 11 of the non-COVID-19 antibodies. The cutoff values for each of the 11 analytes were set using World Health Organization (WHO) standards. For all tests on the panel, antibody units (AbU), a measurement unit developed to simplify the results, are shown for the full panel. A level greater than 120 AbU units is considered protective.

It is important to note several limitations and caveats of the ImmunoProfile Antibody Test System. First, positive results with this assay should not be interpreted as indicating the presence of disease, active infection, or disease stage. A single positive result only indicates the presence of IgG antibodies against the analytes of interest. Second, false-positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Third, studies using known immune and non-immune individuals have not been performed on any of the analytes. Fourth, the claims and performance of the ImmunoProfile Antibody Test System test have not been reviewed, cleared, or approved by the US FDA. It is also important to point out that a positive result for antibodies against SARS CoV-2 Spike Receptor Binding Domain (RBD) may be derived from vaccination and/or a natural infection and may not be representative of neutralizing antibodies. Also, while testing for the presence of antibodies specific to the SARS-CoV-2 NC and RBD antigens is included in the panel, the ImmunoProfile Antibody Test System has not been authorized for use by the FDA under current EUA guidelines related to SARS-CoV-2 testing and, therefore, SARS-CoV-2 results are not reported in the US when the test is used clinically. It also should be noted that positive results for polio virus antibodies do not necessarily indicate the presence of neutralizing antibodies which may be a better indicator of protection.[22–24] A negative result, however, is valuable as it demonstrates that the patient lacks protective antibody including neutralizing antibody to all three poliovirus serotypes. All commercially available polio titers measure only antibody titers to types 1 and 3 because of the low prevalence of type 2 in the US The ImmunoProfile Antibody Test is, therefore, useful for surosurveillance studies outside the US Finally, it must be stated that antibody-mediated immunity does not present the entire picture of protection and that vaccines can elicit T cell responses that contribute to protection from VPDs.[25]

It is important to note that several common VPDs are not included in the panel. These include influenza virus. *Meningococcal meningitidis, Streptococcus pneumoniae* and human papilloma virus. Other vaccines that are only used in special circumstances such as rabies, dengue, yellow fever, anthrax, Japanese encephalitis, typhoid, cholera, adenovirus, etc., are also not included.

Conclusions

Serosurveillance studies for vaccination status are often performed on a disease-by-disease basis. Such studies are obviously critical for understanding the vaccination gaps for a particular disease being studied. Serological survey data obtained with the validated ImmunoProfile Antibody Test System could provide a wealth of information on a given population being tested and could unearth vaccination gaps that may not have been anticipated. Such information could guide immunization programs and thus have a significant impact on efforts to increase vaccination rates and ultimately have a significant positive effect on public health. The availability of this test is, in fact, in line with the Immunization Agenda 2030 of the WHO.[26] Larger serosurveillance studies will be necessary to demonstrate the utility of this MBA as a public health tool. In addition, the ImmunoProfile Antibody Test System provides a useful tool for institutions or government agencies to address vaccine compliance more effectively and for individuals to be better informed of their protective levels of antibody to many VPDs.

Abbreviations

AbU, antibody units; CAP, College of American Pathologists; CDC, Center for Disease Control; CLIA, Clinical Laboratory Improvement Amendments; DBS, Dried blood spots; DPT, diphtheria, pertussis and tetanus; EUA, emergency-use authorization; HAV, hepatitis A virus; HBV, hepatitis B virus; HepBsAg, hepatitis B virus surface antigen; HCP, Health care professionals/providers; IRB, Institutional Review Board; LDT, Laboratory-developed test; MBA, Multiplex bead assays; MFI, Mean fluorescent intensity; MMR, measles, mumps and rubella; NC, nucleocapsid; PE, phycoerythrin; RBD, receptor-binding domain; RUO, Research-use only; VPD, vaccine-preventable disease; WHO, World Health Organization.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

PDO and SG serve as the chief medical officer and chief technology officer of ImmunoProfile, LLC, respectively. RR is a consultant for ImmunoProfile, LLC and also reports a member of the scientific advisory board of the company bringing experience as a nursing educator, healthcare administrator and clinician. The authors report no other conflicts of interest in this work.

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