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Development of Ethical COVID-19 Antibody Testing that Adheres to Pro-Life Principles

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Abstract

The use of cell lines derived from elective abortions in the development and production of COVID vaccines was opposed by the Catholic church who encouraged pharmaceutical companies and governmental health agencies to produce and distribute ethical vaccines that do not create problems of conscience for healthcare providers or those requiring vaccination. In response to the church's call for ethical alternatives in research and development of COVID vaccines, we present an approach for the measurement of Anti–SARS-CoV-2 Ig antibodies in blood plasma (COVID-19 Antibody test) that does not utilize any products produced in aborted fetal cell lines. The SARS-CoV-2 RBD protein used in this test was produced in Chinese Hamster Ovary (CHO) cells and test performance for determination of SARS-CoV-2 seroconversion was equivalent to a commercially available COVID-19 antibody test that utilized RBD protein and other reagents produced in embryonic cell lines.

Keywords

COVID-19, Catholic identity in health care, cooperation with evil, difficult moral questions, medical decision making, medical research, SARS-CoV-2, theology and bioethics, vaccines, COVID-19 antibody testing

Introduction

Emergence of SARS-CoV-2 infections, that quickly spread globally, necessitated immediate research focused on development of vaccines and therapies to minimize hospitalizations and limit deaths from COVID-19. Currently, all COVID-19 vaccines use aborted fetal cell lines either for their development or production (Wadman 2020, 1170–1171) which is not surprising as embryonic cell lines (HEK-293, PER.C6, WI-38, and MRC-5) are

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routinely used for the production of recombinant proteins in research laboratories due to their human origin and ease of gene transfection and cell culture (Wong 2006, 473–495). In addition, previous use of these same aborted fetal cell lines in production of other USFDA approved vaccines for rubella, varicella, hepatitis-A and varicella-zoster (McKenna 2018, 13–17) encourages their use as regulatory requirements for full characterization of "cell substrates" involved in the manufacture of vaccines to assure safety and purity have been met (USFDA 2010).

Although expedient for COVID-19 vaccine development and production, the Catholic Church reiterated its opposition to the use of aborted fetal cell lines in medical research and vaccines (Card and Ladaria 2021, 254–255); a topic which was previously addressed in response to concerns of the morality of the MMR vaccine which uses rubella virus particles produced in the aborted fetal cell line WI-38 (Pontifical Academy for Life 2019, 182–187). Regarding the MMR vaccine, the Church indicated that the use of vaccines generated in aborted fetal cell lines represents a passive [indirect] cooperation with the original illicit act of abortion and creates a "moral coercion of the conscience of the parents, who are forced to act against their conscience or otherwise, to put the health of their children and the population as a whole at risk" (Pontifical Academy for Life 2019, 185). In research laboratories, the use of these cell lines creates a "contradiction in the attitude of the [scientist] who says that he does not approve of the injustice perpetrated by others, but at the same time accepts for his own work the 'biological material' which the others have obtained by means of that injustice." (Congregation for the Doctrine of the Faith 1987) Hence, any association with aborted fetal cell lines, even indirect, should be avoided as beneficiaries are subject to scandal. However, this right should only be exercised if the population as a whole are not subjected to significant health risk (Pontifical Academy for Life 2019, 185). The harm due to severe disease that is preventable by an abortion-associated vaccine presents a "grave inconvenience" that imposes their use on the faithful but only on a "temporary basis" (Pontifical Academy for Life 2019, 182–187). All people of good conscience are obliged to seek ethical alternatives, if available, and to voice opposition to the use of aborted fetal cell lines in research and medicine to encourage the development of alternatives (Pontifical Academy for Life 2019, 182–187).

Revisiting this same issue with COVID-19 vaccines, the Congregation for the Doctrine of the Faith indicated that it is licit to receive any of the currently available vaccines by reaffirming that "the moral duty to avoid passive material cooperation is not obligatory if there is a grave danger, such as the otherwise uncontainable spread of a serious pathological agent."(Card and Ladaria, 2021; 255). Current circumstances imposed their use on the faithful. However, the need for alternatives was also reaffirmed by indicating that "Both pharmaceutical companies and governmental health agencies are therefore encouraged *to produce, approve, distribute and offer* ***ethically acceptable vaccines*** *that do not create problems of conscience* for either health care providers or the people to be vaccinated." (Card and Ladaria 2021, 255).

Encouraging ethical research, free from an association with abortion, is paramount as the continued practice of using aborted fetal cell lines in laboratories assures the continued generation of abortion-associated products. For example, recombinant proteins produced in aborted fetal cell lines are used not only in vaccines but also in biotherapeutics to treat hemophilia (Factors VII and IX) and type II diabetes (GLP-1R agonists) (Dumont et al. 2016, 1110–1122), and in serological assays to test for anti–SARS-CoV-2 antibodies (COVID-antibody tests) (USFDA 2021). Production of recombinant proteins in aborted fetal cell lines is often justified by differences in post-translational modification of recombinant proteins, specifically glycosylation, between human and nonhuman cell lines which can influence antigenicity and function (Dumont et al. 2016, 1110–1122). As the use of

embryonic cell lines is common, it was very difficult to determine which commercially available COVID-19 antibody tests utilized reagents that were produced in aborted fetal cell lines as this information is normally not included in product inserts and, in certain circumstances is considered proprietary. Unable to identify a commercially available COVID-19 antibody test free from association with abortion, we first modified the Seroindex, Kantaro™ SARS-CoV-2 IgG Antibody RUO kit from R&D systems by replacing SARS-CoV-2 RBD protein produced in an embryonic cell line with the same protein produced in Chinese Hamster Ovary (CHO) cells. We then developed a new COVID-19 antibody test, selecting SARS-CoV-2 RBD protein and anti–SARS-CoV-2 antibodies that were not produced in aborted fetal lines. The performance of both COVID-19 antibody tests were equivalent to the original Seroindex, Kantaro™ SARS-CoV-2 IgG Antibody RUO kit indicating that the use of products produced in aborted fetal cell lines was not necessary. The new COVID-19 antibody test represents an effective ethical alternative for determination of SARS-CoV-2 seroconversion that adheres to pro-life principles.

Materials and Methods

Experimental Cohorts

This study was approved by the Franciscan University of Steubenville (FUS) Institutional Review Board, (FUS 2020-10; PI McKenna). After obtaining informed consent, sixty-three participants provided blood specimens during blood draws conducted in November 2020 and completed a list of questions which included their age, sex, whether they experienced COVID-19 symptoms (fever, cough, shortness of breath, and/or loss of smell) since January 2020, and whether they had tested positive for the presence of SARS-CoV-2 in the same timeframe.

Specimens from forty-one participants were selected to optimize anti–SARS-CoV-2 IgG antibody testing. These specimens represented two defined experimental cohorts (Supplemental Table I): participants with a positive nucleic acid amplification test (NAAT) test for SARS-CoV-2 RNA that experienced COVID-19 symptoms ($n = 20$) and, participants that had not experienced COVID-19 symptoms and had not tested positive for the presence of SARS-CoV-2 ($n = 21$). Specimens excluded from analysis included participants whose NAAT+ tests were less than 14 days prior to the blood draw ($n=8$), participants with a NAAT+ test with no COVID-19 symptoms ($n = 2$), participants with COVID-19 symptoms that had not tested positive for the presence of SARS-CoV-2 ($n = 10$), and participants with incomplete records ($n = 2$; one with no birth date provided, one with incomplete antibody testing).

Blood Specimen Collection

Blood specimens (5 mL) were collected into K_2EDTA vacutainer tubes (Becton Dickinson; San Jose, CA) via venipuncture by trained senior nursing students, under direct supervision by FUS Nursing Department faculty, and stored at room temperature. Blood plasma was isolated the following day by centrifugation and stored at -85^{o}C for subsequent analysis. Frozen plasma samples were thawed at room temperature and then incubated at 56^{o}C for 1 hour to inactivate potentially infectious viral particles.

COVID-SeroIndex, Kantaro™ SARS-CoV-2 ELISA

Anti–SARS-CoV-2 IgG responses were determined using the COVID-SeroIndex, Kantaro™ SARS-CoV-2 IgG antibody RUO Kit (R&D Systems, Minneapolis, MN), a two-step enzyme-linked immunosorbent assay (ELISA). In the first step plasma samples were added to wells of a 96-well plate pre-coated with receptor binding domain (RBD) of the SARS-CoV-2 Spike (S) protein. RBD was produced in an embryonic cell line (personal communication, R&D systems technical service, Minneapolis, MN). After a two-hour incubation, wells were washed to remove unbound antibodies and then an enzyme-

linked anti-human IgG antibody was added. After a one-hour incubation, another washing step was performed to remove unbound secondary antibody. A substrate was then added and color developed in wells in proportion to the amount of anti–SARS-CoV-2 IgG antibody bound to RBD. Absorbances at 450 and 570 nm were measured using a spectrophotometer (Tecan, Switzerland). Plasma specimens were run as singlets and compared to kit-provided positive and negative control samples run in duplicates. A cutoff index (CI) was calculated as follows: Corrected Absorbance (450–570 nm) of sample/Corrected Absorbance of RBD positive control = CI. CI ≥0.7 were considered positive for the presence of anti–SARS-CoV-2 RBD IgG antibodies and CI<0.07 were considered negative.

A second orthogonal semi-quantitative ELISA, using 96-well plates pre-coated with whole SARS-CoV-2 S protein was also performed to determine the concentration of anti-S protein IgG antibodies. S protein was produced in a nonembryonic cell line (personal communication, R&D systems technical service, Minneapolis, MN). Plasma samples were run as singlets along with titrated standards run in duplicate. Corrected absorbance values from plasma samples were compared to a calibration curve of standards to determine the concentration of unknown samples expressed in Arbitrary Units per ml (AU/ml). A threshold value of 3.2 AU/ml in plasma specimens diluted 1:200 in provided sample buffer was used to score positive samples. Samples with values >160 AU/ml were positive but outside the analytical range for the anti-S protein IgG ELISA. A specimen was considered positive only if positive results were observed for both phase I (anti–SARS-CoV-2 RBD IgG) and phase II (anti–SARS-CoV-2 S IgG) ELISAs.

Modified COVID-SeroIndex, Kantaro™ SARS-CoV-2 ELISA

High-protein binding Immulon® Microtiter™ 96-well plates (Thermo Fisher Scientific, Waltham, MA) coated with 1 μg/mL RBD antigen produced in CHO cells (R&D systems, Cat #10534-CV) were substituted for Kit-provided 96-well plates pre-coated with RBD antigen that was produced in an embryonic cell line. All other reagents provided in the kit were utilized and kit-provided sample buffer (0.3 mL/well) was added to the substituted RBD plates to block wells by incubation at room temperature for >1 h. The difference in absorbance between kit-provided RBD negative control and 70% of the absorbance of the kit-provided RBD positive control was 30-fold or greater when using either kit-provided RBD ELISA plates or ELISA plates coated with ≥ 1 μg/mL CHO cell derived RBD protein (Supplemental Figure 1).

Semi-Quantitative Anti–SARS-CoV-2 RBD ELISA

Individual wells of high-protein binding Immulon® Microtiter™ 96-well plates (ThermoFisher Scientific) were coated with 1 μg/mL CHO-cell–produced RBD antigen (R&D systems, Minneapolis, MN; Cat #10534-CV) in 0.1 mL PBS by overnight room-temperature incubation. Plates were then washed twice with 0.3 mL ELISA wash buffer (PBS, 0.01% Tween-20) and subsequently blocked by addition of 0.3 mL 3X Blocker™ BSA in PBS (ThermoFisher Scientific; CAT #37525). After a room-temperature incubation of 1 hour, plates were washed twice with ELISA wash buffer and then plasma samples (0.1 mL), diluted 1:100 in 1X Blocker™ BSA in PBS were added to individual wells in duplicate. Following a two-hour incubation at room temperature, plates were washed seven times with ELISA wash buffer and then 0.1 mL of an enzyme conjugated anti-Human IgG antibody (Invitrogen, Waltham, MA; CAT#H10007) diluted 1:50,000 in 1X Blocker™ BSA was added to wells. After a one-hour incubation plates were washed seven times and then 0.1 mls TMB substrate (BD Biosciences, San Jose, CA; CAT#555214) was added to wells and color developed in proportion to the amount of anti–SARS-CoV-2 RBD IgG bound to antigen. The

enzyme reaction was stopped after 20 minutes by addition of 0.1 mL 0.16 M H_2SO_4. Corrected absorbances (450–570 nm) of wells were measured using a spectrophotometer (TECAN, Switzerland) and compared to a standard curve of known concentrations of titrated anti-SARS-RBD monoclonal IgG1 antibody (ThermoFisher Scientific; CAT#703958) diluted in 1X Blocker™ BSA to determine an approximate concentration of anti–SARS-CoV-2 RBD IgG in plasma samples.

Statistical Analysis

Prism (Graph Pad) was used for all analysis and statistical significance was defined as p values <0.05.

Results

COVID-Seroindex Kantaro™ SARS-CoV-2 IgG Antibody RUO Kit Established a Reliable Baseline for Performance Comparison of Anti–SARS-CoV-2 Antibody Tests

The presence of anti–SARS-CoV-2 Ig antibodies in plasma specimens from 20 individuals who experienced COVID-19 symptoms confirmed by a positive NAAT (NAAT+) and twenty-one asymptomatic individuals that had not been tested or received a negative NAAT (Negative) were first evaluated using the COVID-Seroindex Kantaro™ SARS-CoV-2 IgG Antibody RUO kit (COVID-Seroindex) to establish a reliable baseline for performance comparison to our newly developed test that does not use products produced in aborted fetal cell lines. COVID-Seroindex is a two phase semi-quantitative ELISA with 99.8% specificity, 97.8% sensitivity and, measured antibody concentrations correlated with virus neutralization in vitro (Amanat et al. 2020, 1033–1036).

In the first phase, IgG antibodies directed against the RBD domain of the SARS-CoV-2 S protein were evaluated in comparison to a kit-provided positive control to determine cutoff index (CI) values. 18 of 20 specimens from NAAT+ participants had CI ≥ 0.7 indicating the presence of anti–SARS-CoV-2 antibodies, whereas all plasma specimens from Negative participants had CI values below 0.7 and were considered negative (Figure 1A). A 26-fold difference in mean CI was observed between NAAT+ and Negative groups which was statistically significant ($p < .0001$). In the second phase ELISA, IgG antibody responses directed against the whole SARS-CoV-2 S protein were evaluated and, consistent with the results of the first ELISA, 18 of 20 specimens in the NAAT+ group demonstrated antibody responses that were 28-fold greater ($p = .0002$) than observed in specimens from the Negative group (Figure 1B). The two negative specimens in the NAAT+ group were the same specimens that scored negative in the first phase ELISA (Figures. 1A and B, Supplemental Table I). All specimens from the Negative group except for one (indicated in red) demonstrated values that were below the positive threshold indicating 98% concordance between the two ELISAs (Figure 1C).

Modification of the COVID-Seroindex Kit to Remove RBD Protein Produced in an Embryonic Cell Line

The COVID-Seroindex test utilizes 96-well plates pre-coated with RBD (phase I) and whole S (phase II) proteins that were produced in an embryonic and nonembryonic cell lines, respectively (personal communication R&D Systems technical service specialist). To create a test that did not utilize any products produced in cell lines derived from elective abortions, we simply substituted plates coated with CHO-cell–produced RBD for kit-provided RBD-antigen–coated plates. All other materials and procedures indicated in the product datasheet for the COVID-Seroindex test were utilized and maintained. As shown in Figure 2A, 18 of 20 specimens in the NAAT+ group demonstrated CI ≥ 0.7 indicating the presence of anti–SARS-CoV-2 IgG antibodies directed

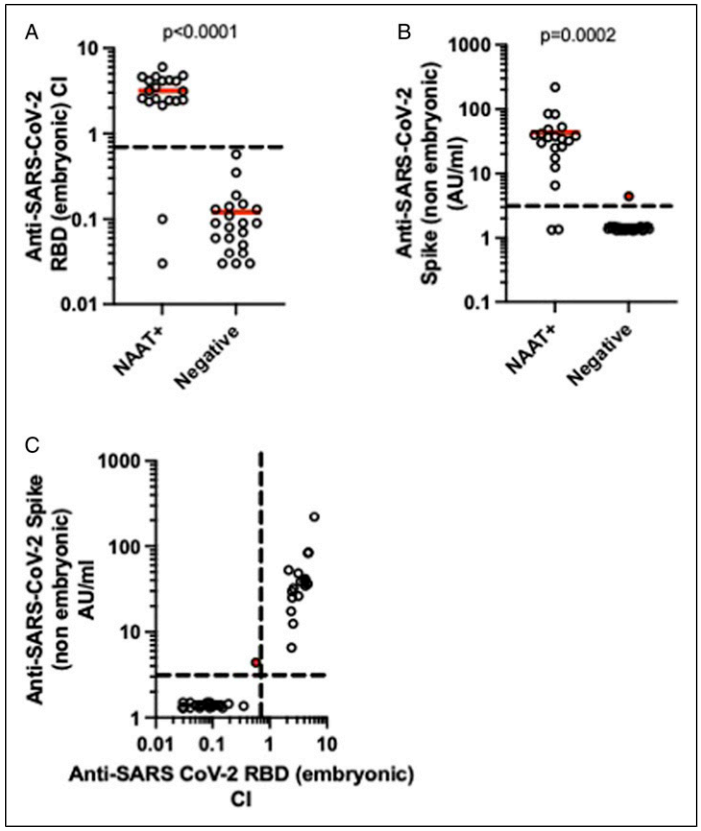

Figure 1. Evaluating SARS-CoV-2 seroconversion by COVID-Seroindex, Kantaro™ SARS-CoV-2 enzyme-linked immunosorbent assay. Plasma specimens from change to symptomatic individuals with a positive NAAT for SARS-Cov-2 RNA (NAAT+) and asymptomatic individuals that were NAAT negative or had not been tested (Negative) were evaluated for the presence of IgG antibodies specific for receptor binding domain (A) and whole Spike protein (B). Concordance of the two measurements was evaluated in C. Each symbol represents a measurement from a plasma specimen of an individual within the NAAT+ (n = 20) or Negative (n = 21) cohorts. Red symbol indicated a specimen with discordant measurements between the two ELISA phases. CI = cutoff index; AU = arbitrary units. NAAT = nucleic acid amplification test = nucleic acid amplification test.

against the RBD domain, whereas all specimens from the Negative group except for one (indicated in red) were below the positive CI threshold. The difference between the mean CI of the two groups was 12-fold and statistically significant ($p < .0001$). The concordance between the substituted RBD (CHO) plates and kit-provided RBD (embryonic cell line derived) plates was 98% with a slope of 1.0 (95% confidence intervals 0.9255–1.155) that was statistically significant ($p < .0001$). The one discordant specimen (indicated in red) was scored negative in phase I but positive in phase II using the unmodified COVID-Seroindex kit (Figures 1B and 1C, Supplemental Table I). Upon completion of this experimentation and manuscript preparation R&D systems disclosed that another reagent (anti-human IgG antibody) was also derived from an embryonic cell line (R&D Systems technical service, personal communication).

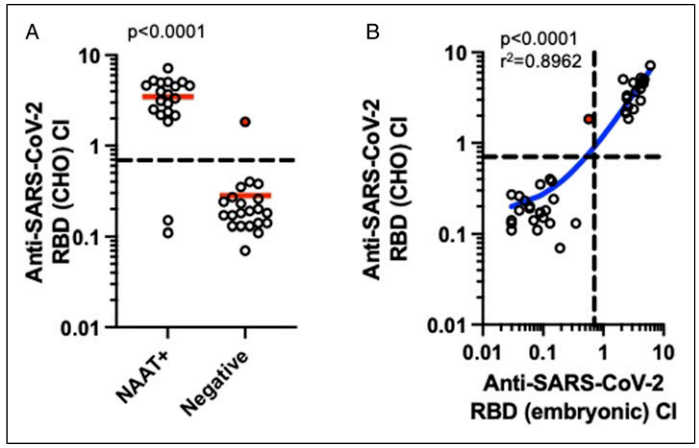

Figure 2. Modified COVID-SeroIndex, Kantaro™ SARS-CoV-2 enzyme-linked immunosorbent assay for evaluation of SARS-CoV-2 seroconversion. Plasma specimens from NAAT+ and Negative cohorts were evaluated for the presence of IgG antibodies specific for RBD that was generated in CHO cells (A). Concordance of anti-RBD IgG measurements made with plates coated with RBD produced in an embryonic cell line (embryonic) and CHO cells is shown in B. Each Symbol represents a measurement from a plasma specimen for an individual within the NAAT+ (n = 20) cohorts. Red symbol indicates a specimen with discordant measurements between the two ELISAs presented in A and B. CI = cutoff index; RBD = receptor binding domain; CHO = Chinese hamster ovary.

Development of a Semi-Quantitative Anti–SARS-CoV-2 Antibody ELISA That Does Not Use Products Produced in Cell Lines Derived From Elective Abortions

To develop a semi-quantitative ELISA to determine an approximation of the concentration of anti–SARS-CoV-2 antibodies directed against the RBD domain that was free of products derived from aborted fetal cell lines, 96-well plates were coated with RBD produced in CHO cells. All other reagents were validated that their source of origin was not an embryonic cell line. Known concentrations of a monoclonal antibody specific for the SARS-CoV-2 RBD were then utilized to generate a calibration curve of corrected absorbances (450–570 nm) versus antibody concentration (Figure 3A). Standards were run in duplicate and the linear range of detection was from 2.0 to 62.5 ng/mL.

Utilizing this new test, the calculated concentrations of anti–SARS-CoV-2 RBD IgG in specimens considered to be negative were 2+/− 1.3 ng/mL. Based on these values a threshold to score positive samples was set three standard deviations above the mean of negative samples at 5.9 ng/mL (Figure 3B, dashed line). Data were presented as arbitrary units/ml (AU/ml) as the concentration of antibodies in specimens is approximated by the calibration curve (Figure 3B). Consistent with the two other presented tests (Figures 1 and 2), 18 of 20 specimens from the symptomatic NAAT+ group scored positive and only one of 21 specimens from asymptomatic Negative participants scored positive (Figure 3B). A 30-fold difference in mean AU/ml was observed between the groups which was statistically significant ($p < .0001$). The one discordant sample that scored positive in the Negative group (indicated in red) was also scored positive by the phase II ELISA of the original COVID-Seroindex kit (Figure 1B and C) and by the modified RBD (Figure 2A). The two negative specimens in the symptomatic NAAT+ group were the same specimens scored negative by the original (Figure 1A) and modified (Figure 2A) Phase I ELISAs and Phase II ELISA of the COVID-Seroindex kit (Figure 1B). Anti–SARS-CoV-2 Ig antibody

measurements from the new semi-quantitative ELISA demonstrated 100% concordance with measurements made with the Phase II ELISA of the COVID-Seroindex kit with a slope of 1.1 (95% confidence intervals = 0.9535-1.285; $p < .0001$) (Figure 3C).

Discussion

In response to the Catholic church's call for ethically produced medical products (Pontifical Academy for Life 2019, 182–187; McKenna 2018, 13-1, Card and Ladaria 2021, 254–255), we describe the development of an ELISA for measuring SARS-CoV-2 IgG in blood plasma that does not use reagents produced in cell lines derived from aborted fetuses. We specifically selected ethically produced and commercially available reagents for the development of a new Anti–SARS-CoV-2 Ig ELISA. This new test performed equivalently to the modified COVID-Seroindex test that used CHO-cell–produced RBD. In addition, we utilized a standard method of indirect ELISA that is easily performed in any Biosafety level II laboratory. The only instrumentation needed is a spectrophotometer.

Our results indicate that RBD protein produced in CHO cells was effective for use in anti–SARS-CoV-2 ELISAs. Why then are aborted fetal cell lines, for example, HEK-293, continually utilized to generate SARS-CoV-2 proteins for laboratory research and COVID vaccines? To begin, HEK-293 are immortalized and therefore they grow perpetually in culture (Thomas and Smart 2005, 187–200). They also grow as a suspension culture and are easy to transfect with gene constructs to express recombinant proteins in high yield (Thomas and Smart 2005). However, these same properties are exhibited by CHO cells (Kunert and Vorauer-Uhl 2012, 213–226). Another reason is that there are differences in post-translation modification of recombinant proteins, specifically glycosylation, when expressed in HEK-293 versus CHO cells including galactose-α1,3-galactose and N-glycolylneuraminic acid additions that, do not occur in human cells and, are potentially immunogenic (Croset et al. 2012, 336–348). Producing recombinant proteins in vitro that are most similar to what is expressed in human beings is logical. In addition, the SARS-CoV-2 S protein, utilized in all COVID vaccines, is heavily glycosylated (Watanabe et al. 2020, 330-333; Shajahan et al. 2020, 981–988) which further supports the use of human cell lines for recombinant protein production. However, other immortalized human cell lines of licit origin could be used (Supplemental Table II). In particular, Jurkat, HL-60, Nalm-6, and K562 cell lines, derived from leukemia patients, also grow in suspension and are easily transfected. A final reason for continued use of aborted fetal cell lines in vaccine development is that they have been previously characterized as safe "cell substrates" for production of other vaccines, thereby expediting FDA regulatory approval (USFDA 2010). However, CHO cells have also been characterized as safe for use in production of the USFDA approved vaccine for shingles, Shingrex (Glaxo Smith Kline) (Lal et al. 2015, 2087–2096). Hence, differences in post-translational modifications of proteins between mammalian cell lines represent the strongest argument for continued use of human cell lines in vaccine development. The familiarity with aborted-fetal cell lines for recombinant protein expression combined with expediency of regulatory approval if used in vaccine production most certainly discourages the use of other cell lines of licit origin. Nevertheless, the improved performance of the Shingrex vaccine which consists of recombinant Herpes Zoster Virus (HZV) glycoprotein E that was produced in CHO cells over the live attenuated HZV vaccine (Zostavax) produced in the MRC-5 aborted fetal cell line (Lal et al. 2015, 2087–2096; Nordén et al. 2019) would suggest at the very least parallel development of vaccines produced in CHO cells.

Discouraging the use of aborted fetal cell lines in medicine and research laboratories is a very difficult task. HEK-293 cells have been used extensively since their development in the 1970's and are commercially available to

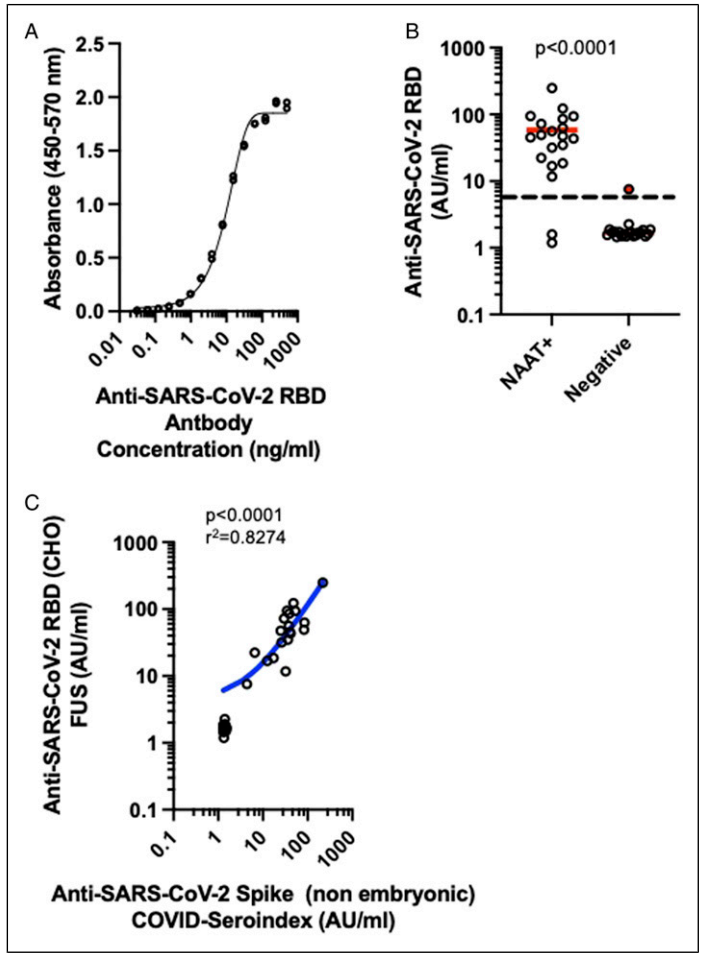

Figure 3. Semi-quantitative anti-RBD IgG ELISA to evaluate SARS-CoV-2 seroconversion. (A) Calibration curve of titrated concentrations of a monoclonal antibody directed against SARS-CoV-2 RBD and their corrected absorbances. Symbol shows duplicate measurements made for each concentration. (B) Approximate concentration of anti–SARS-CoV-2 IgG in plasma specimens from NAAT+ and Negative cohorts. Each symbol represents a measurement from a plasma specimen of an individual within the NAAT+ (n = 20) or Negative (n = 21) cohorts. (C.) Concordance of measurements made by the Franciscan University of Steubenville (FUS) developed test and the COVID-SeroIndex, Kantaro™ SARS-CoV-2 anti-Whole Spike ELISA. ELISA = enzyme-linked immunosorbent assay; RBD = receptor binding domain.

research scientists (Oxgene 2020). Many laboratories utilize validated recombinant proteins produced in HEK-293 that were manufactured in large-scale by established Biotech companies and unquestionably, these cell lines and their products have led to significant scientific discoveries and contributed to development of life-saving therapies (Dumont et al. 2016, 1110–1122). However, it is important to note that HEK-293 was not developed for these purposes. The original derivation of this cell line was for cancer research aimed at understanding the transformation of cells by adenoviruses (Oxgene 2020) which highlights that the prolific use of HEK-293 was primarily utilitarian and not a necessity. Nevertheless, HEK-293 produced proteins have become a "gold standard" in

science. Our direct side-by-side comparison between a COVID-antibody test that utilized products produced in embryonic cell lines and our test that utilized proteins produced in nonembryonic cell lines, demonstrated equivalence in determining SARS-CoV-2 seroconversion. These data clearly indicate that embryonic cell line produced SARS-CoV-2 proteins and reagents are not necessary for determining SARS-CoV-2 seroconversion. Ironically, this comparison imposed the use of reagents produced in embryonic cell lines that we seek to discourage but was necessary to provide convincing evidence to encourage experimentation and medical testing that is both effective and respects the dignity of all human persons, including the unborn, by utilizing a licit cell line that is also a "gold standard" for recombinant protein production (Dumont et al. 2016, 1110–1122).

In conclusion, we present an ELISA for evaluating SARS-CoV-2 seroconversion that does not utilize any products produced in cell lines derived from elective abortions. This anti–SARS-CoV-2 IgG test was comparable to a commercially available COVID-19 antibody test that utilized proteins produced in embryonic cell lines. This COVID-19 antibody test represents an ethical alternative that eliminates the contradiction of conscience presented by the utilization of abortion-associated medical products in COVID-19 antibody tests that evaluate SARS-CoV-2 seroconversion.

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Declaration of Conflicting Interests

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Supplemental Material

Supplemental material for this article is available online.

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