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Agreement of the Point of Care Test (POCT) Boditech iCHROMA™ Covid-19 IgG Antibody Assay with the Abbott Architect SARS-CoV-2 IgG Antibody Assay

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Abstract

Background: The Boditech iCHROMA™ point of care immunoassay analyser has a Covid-19 antibody assay for the qualitative determination of IgG/IgM antibodies in human whole blood/serum/plasma. It is helpful as an aid in the screening of early mild asymptomatic or acute patients for identifying Covid-19 infection with high sensitivity.

Objectives: To determine the clinical agreement (sensitivity and specificity) of the Boditech iCHROMA™ Covid-19 antibody assay and the Abbott Architect SARS-CoV-2 IgG assay for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma.

Results: Of the 50 plasma samples, 20 (40%) of the plasma samples assayed were reported as positive by both the Abbott Architect SARS-CoV-2 IgG assay and the Boditech iCHROMA™ Covid-19 IgG antibody assay. The remaining 30 (60%) of the plasma samples were reported as negative by Abbott Architect SARS-CoV-2 IgG antibody assay. However, the Boditech iCHROMA™ Covid-19 IgG antibody assay, reported only 27 of the 30 (90%) samples as negative.

Conclusion: There was an overall agreement of 95%, with a sensitivity of 100% and a specificity of 90% of the Boditech iCHROMA™ Covid-19 IgG antibody assay and the Abbott Architect SARS-CoV-2 IgG assay.

Keywords: iCHROMA™; Abbott; COVID-19; IgG antibody

Abbreviations: ECDC: European Centre for Disease Prevention and Control; WHO: World Health Organization; RT-PCR: Reverse Transcription Polymerase Chain Reaction; FIA: Fluorescence Immunoassay; CMIA: Chemiluminescent Microparticle Immunoassay; PPA: Positive Percent Agreement; NPA: Negative Percent Agreement; IgG: Immunoglobulin class G; CMIS; Chemiluminescent Microparticle Immunoassay; RLU: Relative Light Unit; CMIA: Chemiluminescent Microparticle; FIA: Fluorescence Immunoassay.

Introduction

Timely and accurate testing is crucial in the management of the COVID-19 pandemic. The European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO) recommend the reverse transcription

polymerase chain reaction (RT-PCR) on nasal, oropharyngeal secretions as the gold standard diagnostic tool for COVID-19 [1]. However, this method does have its challenges: preanalytical and analytical [2]. The pre-analytical issues include identification problems, inadequate procedures for collection, handling, transport and storage of swabs, collection of inappropriate or inadequate material, presence of interfering substances, manual errors, as well as sample contamination. The analytical aspects that also contribute to this challenge include testing outside the diagnostic window, active viral recombination, use of inadequately validated assays, insufficient harmonization along with other specific technical issues [2]. Molecular tests are generally not suited for public health screening, antibody tests are more suited and the more portable, the better. A very versatile point of care immunoassay analyser, the Boditech iCHROMA™ has been shown to compare very well with traditional laboratory methods for PSA, Vitamin D, HCG, FSH, LH, TSH, Testosterone, CRP, Microalbumin and Ferritin [3-10]. Recently, Boditech launched a Fluorescence Immunoassay (FIA) for the qualitative determination of IgG/IgM antibodies against "Novel Coronavirus" in human whole blood, serum, and plasma. There is no gold standard assay to evaluate antibody tests with, so we decided to evaluate the Abbott Architect SARS-Cov-2 IgG assay which is a Chemiluminescent Microparticle Immunoassay (CMIA) used for qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma on the Architect 1 System recently evaluated by Public Health England (PHE) [11,12]. We conducted a study on members of staff and patients' blood samples of a general practice during the Covid-19 pandemic period, with their consent for Covid-19 testing, to determine the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) between the Boditech iCHROMA™ IgG/IgM antibody assay and the Abbott Architect SARS-Cov-2 IgG assay. Both methods IgG assays are designed to detect Immunoglobulin class G (IgG) antibodies to the nucleocapsid protein of SARS-Cov-2.

Materials & Methods

Methods

Boditech iCHROMA™ Method Principle: The test uses a sandwich immunodetection method; fluorescence labelled conjugates in a dried detection buffer binds to antibody in sample, forming antibody-antigen complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilised anti-human IgG on test strip. The more antigen-antibody complexes lead to stronger fluorescence signal by the detector antigen which is processed by the iCHROMA™. The iCHROMA™ processes the signal using a cut off index of 0.9-1.1, results <0.9 are interpreted as negative, results between 0.9 and 1.1 are interpreted as indeterminate and results >1.1 are interpreted as positive. The Data for the Boditech iCHROMA™ IgM was not reported as there was no Comparative Data.

Abbott Architect Method Principle: The assay is an automated, two step immunoassay to detect qualitatively IgG antibodies to SARS-Cov-2 in plasma and serum samples using a Chemiluminescent Microparticle Immunoassay (CMIS). The resulting chemiluminescent reaction is measured as a Relative Light Unit (RLU). There is a direct relationship between the amount of the IgG antibodies to SARS-Cov-2 in the sample and the RLU detected by the system optics. The relationship is reflected in the calculated index (S/C). The presence or absence of the IgG antibodies to SARS-Cov-2 in the sample is determined by comparing the chemiluminescent RLU in the reaction to the calibrator RLU. Abbott Architect processes using a cut off index of 1.4, results <1.4 are interpreted as negative, results >1.4 are interpreted as positive.

Materials

Fifty serum samples were collected from staff and patients of a GP practice (with their consent for Covid-19 testing) with and without symptoms of Covid-19. The patients that were highly suspected of having Covid-19 had their swab samples taken and the samples were sent to a private laboratory to have SARS-Cov-2 PCR assay done.

The serum samples from the study population were taken to a private laboratory where they were tested using the SARS-CoV-2 IgG Abbott Architect assay on the Abbott Architect 1 and then run the next day using the Boditech iCHROMA™ IgM/IgG assay described below:

1. Transfer 150µL of detector diluent using a pipette into the detector tube containing a granule. When the granule is completely dissolved it becomes the detection buffer.
2. Aspirate 10µL of whole blood/serum/plasma/control with a pipette, and add into the detector tube, close and shake the tube at least 10 times.
3. Pipette out 75µL of the content of the tube and load it into the sample well on the test cartridge and leave or 10 minutes.
4. Insert the test cartridge into the cartridge holder in iCHROMA™ device and press start
5. Read the result on the display screen of the iCHROMA™ device.

Results

Clinical Sensitivity

Of the 50 plasma samples collected, 20 (40%) of the plasma samples assayed using the SARS-CoV-2 IgG Abbott

Architect assay, had cut off index >1.4 and were reported as positive, the indices ranged calculated on the positive samples ranged between 1.49 and 9.12. The Boditech iCHROMA™ Covid-19 IgG assay using the cut off index >1.1, reported the same 30 (100%) samples as positive with the indices ranging between 22.8 and 74.6, see Tables 1 & 2.

Specimen No.	Abbott Architect		Boditech iCHROMA™	
	IgG Result	Index	IgG Result	Index
3015	Positive	9.12	Positive	42.2
3019	Positive	4.5	Positive	42.4
3022	Positive	7.29	Positive	34.7
3036	Positive	7.99	Positive	43.6
3045	Positive	3.63	Positive	37
3046	Positive	1.49	Positive	22.8
3049	Positive	3.22	Positive	44.8
3053	Positive	3.61	Positive	37.9
3061	Positive	5.98	Positive	48.5
3062	Positive	2.98	Positive	42.3
3064	Positive	5.26	Positive	32
3066	Positive	5.93	Positive	43.3
3074	Positive	2.24	Positive	47.2
3084	Positive	6.36	Positive	41.4
3087	Positive	6.93	Positive	40.3
3089	Positive	8.19	Positive	74.6
3090	Positive	6.52	Positive	46.4
3092	Positive	7.39	Positive	38.9
3747	Positive	5.63	Positive	40.8
3749	Positive	5.39	Positive	46.5

Table 1: Showing the positive sample cohort and their IgG result and their respective index.

Specimen No	Abbott Architect		Boditech iCHROMA™	
	IgG Result	Index	IgG Result	Index
3021	Negative	0.05	Negative	<0.01
3035	Negative	0.04	Negative	<0.00
3041	Negative	0.12	Negative	<0.00
3042	Negative	0.06	Negative	<0.00
3043	Negative	0.04	Negative	<0.00
3044	Negative	0.08	Negative	<0.00
3048	Negative	0.05	Positive	10
3055	Negative	0.01	Negative	<0.00
3063	Negative	0.04	Negative	<0.00
3065	Negative	0.02	Negative	<0.00
3067	Negative	0.09	Negative	<0.00
3069	Negative	0.02	Negative	<0.00
3075	Negative	0.01	Negative	<0.00

3076	Negative	0.03	Negative	<0.00
3077	Negative	0.02	Negative	<0.00
3078	Negative	0.04	Negative	<0.00
3079	Negative	0.02	Negative	<0.00
3080	Negative	0.02	Negative	<0.00
3091	Negative	0.15	Negative	<0.00
3748	Negative	0.07	Negative	<0.00
3737	Negative	0.04	Positive	4.8
3736	Negative	0.71	Positive	14.8
3735	Negative	0.02	Negative	<0.00
3738	Negative	0.03	Negative	<0.00
3739	Negative	0.02	Negative	<0.00
3742	Negative	0.08	Negative	<0.00
3741	Negative	0.01	Negative	<0.00
3740	Negative	0.02	Negative	<0.00
3746	Negative	0.01	Negative	<0.00
3745	Negative	0.02	Negative	<0.00

Table 2: Showing negative sample cohort and their respective IgG result and index.

Clinical Specificity

Of the 50 plasma samples collected, 30 (60%) of the plasma samples assayed using the SARS-CoV-2 IgG Abbott Architect assay had cut off index <1.4 and were reported as negative the indices ranged calculated on the negative samples ranged between 0.01 and 0.71. The Boditech iCHROMA™ Covid-19 IgG assay using the cut off index <1.1, reported 27 of the 30 (90%) samples as negative with an index of <0.00. Three of the 30 (10%) had a cut off index <1.1, the index of 4.8, 10 and 14.8 was reported as positive see Tables 3 & 4.

The clinical sensitivity and specificity were calculated based on Tables 3 & 4.

		Abbott Architect Covid 19 IgG Antibody		Total
		Positive	Negative	
Boditech iCHROMA Covid 19 IgG antibody	Positive	a	b	a+b
	Negative	c	d	c+d
Total		a+c	b+d	N

Clinical specificity (%) = ({d/(b+d)} x 100)
Clinical sensitivity (%) = ({a/(a+c)} x 100)
Table 3: Shows how the clinical sensitivity and specificity are calculated from the Table 4.

		Abbott Architect Covid 19 IgG Antibody		Total
		Positive	Negative	
Boditech iCHROMA Covid 19 IgG antibody	Positive	20	3	23
	Negative	0	27	27
Total		20	30	50

Clinical specificity (%) = ({27/(3+27)} x 100) = 90%
Clinical sensitivity (%) = ({20/(20+0)} x 100) = 100%
Table 4: Shows the actual numbers achieved.

Conclusion

This study is the first to describe the agreement of the Boditech iCHROMA™ Covid 19 IgG antibody assay method in comparison with the Abbott Architect SARS-CoV-2 IgG. Both the Abbott Chemiluminescent Microparticle (CMIA) IgG immunoassay and the Boditech Fluorescence Immunoassay (FIA) IgG Immunoassay methods assays are designed to detect Immunoglobulin class G (IgG) antibodies to the nucleocapsid protein of SARS-Cov-2. There was 100% agreement of the presence of IgG antibodies in the samples to Cov-19 between the Boditech iCHROMA™ Covid 19 IgG antibody assay method and the Abbott Architect SARS-CoV-2 IgG (Clinical Sensitivity). There was 90% agreement of the absence of Cov-19 IgG antibodies in the samples between the Boditech iCHROMA™ Covid 19 IgG antibody assay and the Abbott Architect SARS-CoV-2 IgG (Clinical Specificity). There were 3(10%) of the samples that were reported as positive by the Boditech iCHROMA™ Covid 19 IgG antibody assay method but negative by the Abbott Architect SARS-CoV-2 IgG, Interestingly using the Boditech iCHROMA™ Covid 19 IgG antibody assay the cut off indices observed in the samples were the lowest observed of 4.8,10 and 14.8, which were generally greater than 20. Looking at the 3 samples reported as positive by the Boditech iCHROMA™ IgG antibody assay, one of the three samples using the Abbott Architect SARS-CoV-2 IgG assay had a high index of 0.71 compared to the others that were generally less than 0.15. A possible explanation for this discrepancy between the methods, considering that both IgG assays were designed to detect immunoglobulin class G (IgG) antibodies to the nucleocapsid protein of SARS-Cov-2 is described in an observation found in the evaluation study carried out by PHE [11,12]. The Abbott Architect SARS-CoV-2 IgG assay, when evaluated by PHE, demonstrated a specificity of 99.63% and a sensitivity of 93.90% at 14 days after symptoms onset that drops off to 93.40% at 21 days and 87.5% at 40 days. It appears that the Abbott Architect SARS-CoV-2IgG assay could give rise to false negatives. Therefore, these samples detected as positive by the Boditech iCHROMA™ Covid 19 IgG antibody assay could be the false negatives of the Abbott Architect SARS-CoV-2 IgG assay.

In this study, we have been able to demonstrate that Boditech iCHROMA™ Covid 19 IgG antibody assay showed an overall agreement of 95%, sensitivity of 100% and specificity of 90% with the Abbott Architect SARS-CoV-2 IgG assay.

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