Study title: Implementation of COVID-19 Point-of-Care diagnostics—knowledge, attitudes, and perceptions among healthcare professionals in Germany.

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FOR ENROLMENT OF ADULTS AGED OVER 18 YEARS-OLD IN COVID-19 POCT SURVEY

ADULT

Funding	MWK (Ministerium für Wissenschaft, Forschung und Kunst) Baden-Württemberg)
Investigators	Dr. med. Claudia Denkinger, Heidelberg University Hospital, Germany; Dr. Ivonne Morales Benavides, Heidelberg University Hospital, Germany; Hannah Tolle, Heidelberg University Hospital, Germany; Dr. Andreas Deckert, Heidelberg University Hospital, Prof. Dr. Till Bärnighausen, Heidelberg University Hospital, Germany
E-mail address	COVID19poct-studie@uni-heidelberg.de

Information Sheet Version Number: V1.0	Date: 13.07.2022

Before you decide whether to take part, please read the following information carefully. Please contact the study staff about anything you do not understand or anything you want to learn more about. If you agree to take part, you will be asked to indicate your eligibility on the survey form.

Dear Sir or Madam,

*We would like to invite you to consider participating in the survey study entitled: '**Implementation of COVID-19 Point-of-Care diagnostics—knowledge, attitudes, and perceptions among healthcare professionals in Germany.'***

This study is organized by scientists in Germany and aims to recruit study participants during a period of 2 months. This study is funded by the MWK (Ministerium für Wissenschaft, Forschung und Kunst) Baden-Württemberg.

1. **Introduction**

Point-of-care (**POC**) **testing** is defined as medical diagnostic testing at or near the point of care—that is, at the time and place of patient care. Unlike conventional diagnostics, POC testing may deliver results within minutes, facilitating mass screening of samples as in the case of SARS-CoV-2. By providing a quick diagnosis, POC testing may also help prevent unnecessary patient and healthcare worker exposure, particularly in settings where vulnerable patient populations or individuals at high-risk of infection congregate, such as oncology, hematology, nephrology, geriatric, and pediatric units, as well as in emergency departments and dialysis units.

Although POC testing has proven to be beneficial in expediting clinical decision making, reducing the time to diagnosis and patient isolation as well as reducing the number of health care related infections in studies, skepticism remains among healthcare professionals, primarily due to the organizational and logistical challenges associated with their use.

2. **What is the purpose of this study?**

We would like to gain insight into the knowledge, attitudes, and perceptions towards COVID-19 POC testing implementation among healthcare professionals working in Germany.

3. **Your participation in this study is voluntary**

Before you agree to participate, it is important that you read and understand the explanation of the purpose of the study, the study procedures, benefits, risks, discomforts, and precautions as well as your right to withdraw from the study. This information leaflet is to help you decide if you would like to participate.

If you have any questions, do not hesitate to contact a staff member.

4. **What will be done during the study?**

Adults who are found to be eligible and agree to take part in the survey will be asked to complete an online survey containing 41-75 items in one single online session. The survey will take approximately **45 minutes** to complete.

The items consist of closed-ended and open-ended questions to enable you to share your perceptions and experiences with COVID-19 POCT.

The questionnaire will also collect some demographic information, including your age, gender, and profession.

5. **Are there risks associated with participating in this study?**

There are minimal or no health risks associated with participating in this survey study. Some questions may evoke memories of a stressful nature, which may result in personal discomfort.

6. **Are there benefits from participating in this study?**

Your participation in this study will contribute to knowledge that may help us identify important attitudes, perceptions, barriers, and facilitators towards the implementation of COVID-19 POC testing. This information will enable us and others to design strategies for the implementation of POC testing in the context of SARS-COV-2—and potentially, other infectious diseases—in emergency and inpatient/outpatient clinical settings.

7. **What are your rights as a participant in this study?**

A. Voluntary participation

Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason.

B. Withdrawal:

You may withdraw from the study at any time by choosing not to submit your survey.

If you withdraw by not submitting your survey, no data will be saved. Because we will not collect identifying information that will allow us to specifically identify you, we cannot delete your survey responses once you submit them.

8. **What are the costs for participating in this survey?**

There is no cost to you for taking part in this survey.

9. **Information about data protection**

- **Collection of information**: During the study, data will be collected and stored on the REDCap electronic platform. No personal information will be collected from you. All information obtained during this study from you as well as information resulting from this study may be shared among study staff. However, study staff are subject to strict confidentiality rules.

- **Data storage:** all the survey data will be stored in password protected databases at Heidelberg University Hospital or in a secure location in anonymized form. All analyses are also performed exclusively in anonymized form. The study's principal investigator, PD Dr. med Claudia Denkinger, and Frank Tobian, MSc, will be in charge of the safety and management of the central database and will take all reasonable steps to ensure that your data is protected in accordance with the data protection standards of the European Union. All data collected during the study will be stored for a period of 5 years.

- **Use of data and future studies:** All research data collected in this study may be used to prepare reports for publication in scientific journals. Such data will not include any information that identifies you as a participant in this study. The data is protected against unauthorized access. The data provided by you or collected as part of this study will be used primarily to address the questions outlined in this study. In the future, however, further investigations with this data may be required and which may be addressed by other research projects related to point of care diagnostics or COVID-19. These future research projects will be discussed separately by the relevant ethics committee. No new informed consent will be obtained from you.

- **Your rights:** We will not collect identifying information that will allow us to specifically identify you or your survey answers. For the same reason, we cannot change your answers or delete your survey responses once you submit them.

The person responsible for the study-related collection of data management is:

Frank Tobian, MSc
Heidelberg University Hospital
Division of Tropical Medicine
Im Neuenheimer Feld 672
69120 Heidelberg, Germany
Tel: +49 (0)6221 56-22999

If you have questions / concerns regarding the processing of your data or data safety regulations, you can contact the following data security officers:

Data security officer of Heidelberg University Hospital:
Heidelberg University Hospital
Datenschutzbeauftragte
Im Neuenheimer Feld 672
69120 Heidelberg, Germany
Tel: +49 6221 56 7036
E-Mail: datenschutz@med.uni-heidelberg.de

In case of illegal data processing, you have the right to complain to the following supervisory authority:

Der Landesbeauftragte für den Datenschutz und die Informationsfreiheit Baden- Württemberg
Postfach 10 29 32, 70025 Stuttgart
Königstraße 10a, 70173 Stuttgart
Tel.: 0711/61 55 41 – 0
Fax: 0711/61 55 41 – 15
E-Mail: poststelle@lfdi.bwl.de
Internet: http://www.baden-wuerttemberg.datenschutz.de

10. **Study results**

Participants of the study have the opportunity to be informed about the general outcome of the study. To do so, they are asked to contact an investigator or study coordinator. It is foreseen that results of this study will be communicated through a publication in a peer-reviewed scientific journal.

ETHICAL APPROVAL:

This study protocol has been submitted to the Ethics Committee of Heidelberg University and written approval has been granted.

SOURCE OF ADDITIONAL INFORMATION:

If at any time during your participation in the study you have any questions, please do not hesitate to contact the investigators at the study site.

For more information, you may contact the principal investigator:

PD Dr. med. Claudia Denkinger
Head of Section Clinical Tropical Medicine
Heidelberg University Hospital
Im Neuenheimer Feld 324
69120 Heidelberg
E-mail address: COVID19poct-studie@uni-heidelberg.de
+49 (0)6221-56-22999

Or the local study coordinator:

Dr. Ivonne Morales Benavides
Section Clinical Tropical Medicine
Heidelberg University Hospital
Im Neuenheimer Feld 324
69120 Heidelberg
E-mail address: COVID19poct-studie@uni-heidelberg.de
+49 (0)6221-56-22999