EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG)

QUESTIONS & ANSWERS	LINKS / REFERENCES

SPECIMEN MANAGEMENT

1 What is the specimen of choice?

serum, plasma, dried capillary blood (DBS)

2 List other specimens which can be used:

serum, plasma, dried capillary blood (DBS)

3 What is the preferred sample collection device?

Blood sample container

4 List other recommended specimen collection device(s), if any:

EUROIMMUN Dried Blood Spot card

5 What are the appropriate storage conditions for the collected samples?
(Please indicate the recommended temperature range for specimen storage and transportation.)

serum/plasma samples: Stability of the patient samples: • stored at +2°C to +8°C: up to 14 days • incubate diluted samples within one working day
DBS: Stability of the patient samples: When stored in a sealed plastic pouch with desiccant bag, the blood spots to be analysed are stable for up to 3 weeks after

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SPECIMEN MANAGEMENT

6 **How long can the specimen be allowed to stand before processing?**

incubate diluted serum/plasma samples within one working day

7 **Are there any key points which require additional attention during the specimen collection process to obtain high quality specimens for your test? Please indicate below, if any.**

DBS: extraction of the sample has to be done as stated in the IFU

8 **Can saline solution be used if no viral transport media is available?**
(If yes, indicate how much time is recommended for the sample to stay in the saline solution.)

REAGENT AND EQUIPMENT MANAGEMENT

9 **What are the storage requirements of the device/kit?**
(Please indicate any temperature, humidity, and any other applicable storage requirements.)

The test kit has to be stored at a temperature between +2°C and +8°C, do not freeze. Unopened, all test kit components are stable until the indicated expiry date.

10 **How stable is the device/kit after opening?**
(Please indicate if the shelf life upon opening varies with the originally assigned shelf life.)

After opening, the reagents are stable until the indicated expiry date when stored at +2°C to +8°C and protected from contamination, unless stated otherwise below.

11 **What are the power and installation requirements of the equipment?**
(Please indicate electrical [input voltage, UPS, etc.], as well as installation, requirements, if any.)

Additional materials and equipment (not supplied in the test kit): • Automatic microplate washer: recommended. Washing of the microplates can also be carried out manually. • Microplate reader: wavelength of 450 nm, reference wavelength range from 620 nm to 650 nm • Calibrated pipettes • Pipette tips

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REAGENT AND EQUIPMENT MANAGEMENT

12 **What is the throughput of the test system per 8hr-work schedule, keeping in mind that we need to ramp up testing in all the community settings?**
(Please indicate the minimum and maximum number of tests [samples and controls] that can be performed per run as well as the expected time per run.)

With each kit 93 patient samples can be analyzed in single measurements. The incubation time is around 2 hrs. Please note that automation can be used for a higher high throughput

13 **What is the turn-around time for the test?**

Around 2hrs

14 **Is calibration required?**
(If yes, please indicate how often, as well as where and how calibration support can be obtained.)

No. But with each run one calibrator (ready to use) and the controls should be included.

15 **How often is maintenance/servicing required?**
(Please indicate any maintenance/servicing support if available.)

16 **Is the device/equipment/kit a standalone or does it require complimentary lab equipment?** (Mention any required accessories.)

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17 **Can the equipment/device/platform accommodate other programs/modules which are not specifically designed by your company?**
(Please describe the compatibility of your device/equipment with other programs, as well as samples [e.g. genetic material] originating from different protocols.)

REAGENT AND EQUIPMENT MANAGEMENT

18 **Can kits from another company be used on your equipment?**

Yes, these are open systems.

19 **Is technical/troubleshooting support available for the device/equipment?**
(If available, please specify the type of support [online, telephone, in-person, etc.].)

Yes.

PERFORMANCE CHARACTERISTICS

20 **What are the performance characteristics of the test for COVID-19?**
(Please provide numerical values.)

A comprehensive report of the performance characteristics of the EUROIMMUN Anti-SARS-CoV-2 ELISAs (IgG) can be found in the test inserts. The sensitivity in samples collected after day 10 of the Anti-SARS-CoV-2 ELISA (IgG) was 94.4% . The specificity was analyzed using >200 samples of patients, positive for

21 **What is the limit of detection of the test?**

ratio 0.14

BIOSAFETY

22 **Is a biosafety cabinet required for the test?**

Please follow the national regulatory rules

23 **What biosafety level is required to perform the test or operate the device ( )?**

24 **How should kit components/devices be disposed?** (Please indicate if there is any kit component that contains chemicals for which additional attention is required.)

Patient samples, calibrators, controls and incubated microplate strips should be handled as infectious waste. All reagents must be disposed of in accordance with local disposal regulations.

TEST SYSTEM / PROCEDURES / CONTROLS

25 **What is the underlying technology?** (Please specify [PCR, IgG/IgM capture, etc.].)

ELISA - IgG antibody detection

26 **Are there any steps in the procedure which require particular reaction conditions?**
(Please specify any temperature and humidity-sensitive incubations.)

The test should be processed at 37°C. The binding activity of the antibodies and the activity of the enzyme used are temperature dependent. It is therefore recommended using a thermostatically adjusted ELISA incubator in all incubation steps. The higher the room temperature during the incubation steps, the greater

27 **What are the indicators of a successful test?**

Valid results of the calibrator and the controls, which come with the QC certificate of the kit.

28 **What are the indicators of a failed run?**

Invalid results of the calibrator and/or the controls, which come with the QC certificate of the kit.

29 **What factors could potentially affect the test?**
(Describe the stability of the test with factors including but not limited to: viral transport media, anticoagulants [for serological assays], heat/chemical inactivation, etc.)

• The pipetting volumes, incubation times, temperatures, and preparation steps given in the instruction for use must be adhered to. • Correct performance of sample collection and storage is crucial for the test results. • The test system is validated for the determination of anti-SARS-CoV-2 IgG in human serum, plasma or dried blood spots only. • The binding activity of the antibodies and the activity

30 **Does the system incorporate controls? If so, how many?** (Please describe.)

Yes, one negative and one positive control (ready to use)

RESULT INTERPRETATION / REPORTING

31 **Is the COVID-19 interpretative software readily available?**
(Please indicate if it comes with the equipment/device or if it has to be purchased separately.)

A device has to be purchased separately.

32 **Can results be transmitted directly from the system without the need to print or keep paper models?**

This depends on the labs LIMS system.

CROSS-CUTTING

33 **Please, as a result of the COVID-19 pandemic, can you tell us what will be the various uses of all the laboratory diagnostic equipment produced as a result of this virus?**

34 **How many manufacturing sites does have for production of this respiratory panel globally? And how would you evaluate production capacity?**

35 **Have you done any analysis of one target (1 N-gene target) vs 2 targets (2 N-gene or 1 N-gene + other)?**

36 **Does** Anti-SARS-CoV-2 ELISA (IgG) **have WHO pre-qualification already?**

No.

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CROSS-CUTTING		
37	**Do you intend to submit to WHO for its Emergency Use Listing procedure?** Yes.	
38	**Is syndromic testing being repeatedly referenced in comparison to surveillance testing, i.e. is its use case intended specifically to triage symptomatic cases in a healthcare setting?**	
39	**Are there plans to introduce other diagnostic RT-PCR panels eventually? Tropical diseases, neuro, neonatal sepsis, etc.?**	
40	**Does the platform have an autonomy from power supply?**	
41	**Are the two options presented today available outside the US or are there are limitations on access to US diagnostics?** Anti-SARS-CoV-2 ELISA (IgG) has FDA EUA and is available in US as IVD.	
42	**Any validation with conventional PCR method? Or, what gold standard test can be used for comparative study at this time?**	

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43	Is the fact of too many targets by too much for a test to use in emergencies?	
44	How do we predict the mutation in the target region that affects the performance of the assay?	
45	When E-gene only amplifies, how do you report it?	
46	Which of these targets are used for confirmation of SARS-CoV-2?	
47	Which gene target is specific for Covid-19?	
48	What are the implications of very high CT positive results?	

Do you have any further comment(s) about your test device/equipment? Please provide comments in the space below.