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Lieferung & Zahlungsart

siehe unsere Liefer- und Versandbedingungen

Zuschläge

· Mindermengenzuschlag
· Trockeneiszuschlag
· Gefahrgutzuschlag
· Expressversand

SZABO-SCANDIC HandelsgmbH
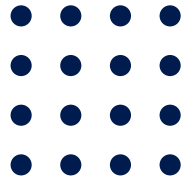
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QUANSYS
B I O S C I E N C E S

Q-Plex™ ARRAY
SARS-CoV-2 Human IgG (4-Plex)

QUANSYS

B I O S C I E N C E S

TABLE OF CONTENTS

Symbol	Explanation
REF	Catalog Number
LOT	Lot Number
	Use By YYYY-MM-DD
	Temperature Limitation
	Manufacturer
	Keep Away From Sunlight

Manufactured and Distributed by:
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For International Distributors see:
http://www.quansysbio.com/distributors

NAME AND INTENDED USE

Q-Plex™ SARS-CoV-2 Human IgG (4-plex)
Quansys Biosciences Catalog Number 691649HU

The Q-Plex™ SARS-CoV-2 Human IgG (4-plex) is a qualitative chemiluminescent assay (ELISA) allowing concurrent measurement of human IgG antibodies to SARS-CoV-2 S1 and SARS-CoV-2 S2 proteins in serum and plasma samples.

- This test is for use by research or clinical laboratories.

- This test has not been reviewed by the FDA.

- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

- Not for the screening of donated blood.

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PRINCIPLE OF THE ASSAY

This multiplex assay is based on the microplate indirect enzyme immunoassay technique for the measurement of Human IgGs reactive to SARS-Cov2 S1, SARS-Cov2 S2, Sheep Fc (negative control), and total Human IgG (positive control).

The microplate is arrayed with 4 spots in each well:

1. SARS-CoV-2 Spike Glycoprotein (S1), a recombinant antigen which contains amino acids 1-674 of subunit 1. Spike S1 is expressed in mammalian HEK293 cells with a Sheep Fc-Tag.

2. SARS-CoV-2 Spike Glycoprotein (S2) is a recombinant antigen which contains the Spike subunit 2 protein, amino acids 685-1211. Spike S2 is expressed in mammalian HEK293 cells with a Sheep Fc-Tag.

3. Sheep Fc, is a negative control to ensure no cross-reactivity occurs between human IgGs in the sample and the Fc-Tag on the SARS-Cov-2 Spike proteins.

4. Anti-Human IgG is a positive control to ensure the kit performs and the IFU was followed correctly.

Samples or controls are pipetted into wells of an arrayed microplate thereby immobilizing antibodies to SARS-CoV-2 S1, SARS-CoV-2 S2, Sheep Fc (negative control), and Human IgGs (positive control) to their locations in the array. After washing away any unbound IgG, a mixture that contains biotinylated anti-human IgG is added. After washing away unbound biotinylated antibody, streptavidin-horseradish peroxidase (SHRP) is added. Following an additional wash, the amount of SHRP remaining on each location of the array is proportional to the amount of Human IgG antibody reactive to SARS-Cov2 S1, SARS-Cov2 S2, Sheep Fc (negative control), anti-Human IgG (positive control) initially captured.

The amount of conjugated enzyme on each location of the array is measured with the addition of a chemiluminescent substrate.

SAMPLE COLLECTION AND STORAGE

The sample collection and storage conditions are intended as general guidelines. Sample stability has not been evaluated.

Serum - Use a serum separator tube (SST) and allow samples to clot for 30 minutes before centrifugation for 15 minutes at 1000 x g. Remove serum and assay immediately or aliquot and store samples at ≤ -20°C. Avoid repeated freeze-thaw cycles.

Plasma - Collect plasma using EDTA, Citrate, or Heparin as an anticoagulant. Centrifuge for 15 minutes at 1000 x g within 30 minutes of collection. Assay immediately or aliquot and store samples at ≤ -20 °C. Avoid repeated freeze-thaw cycles.

IMPORTANT PRECAUTIONS

1. Read all instructions before beginning test.

2. For research use only. Not for use in diagnostic procedures.

3. The kit should not be used beyond the expiration date on the kit label.

4. If running multiple kits, control samples must be included for each 96-well plate. The control values from one plate cannot be used to determine sample results from other plates.

5. Do not mix or substitute reagents with those from other kits or lots.

6. All products are carefully validated, however due to the variability encountered in biological buffers and sample matrices, the possibility of interference or sample matrix effects cannot be excluded.

7. Warning: The controls contain components of human origin. These components have either been tested at the donor level and found negative for HBsAg, HIV-1 and HIV-2 antibodies, and HCV, or they have been heat inactivated. However, consider all materials as potentially infectious and use only approved guidelines for the proper handling and disposal of infectious material.

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DO

- Do set up and practice using the Q-View™ Imager Pro or Q-View™ Imager LS before starting the assay.

- Do dilute all samples at least 1:100 (one part sample to ninety-nine parts diluent) with the provided sample diluent to prevent false positives, and mix thoroughly.

- Do pre-wet pipette tips three times by drawing up the liquid into the pipette and then dispensing back into the original vessel prior to the addition of samples or controls to the microplate.

- Do load all controls and samples into the microplate within 10 minutes of each other.

- Do be exact with incubation times, particularly the streptavidin-horseradish peroxidase (SHRP) incubation.

- Do be exact when mixing Substrate A and B+ and mix thoroughly.

DO NOT

- Do not allow the plate to dry out between steps.

- Do not allow the substrate or SHRP to be exposed to UV light, as this may degrade it.

- Do not incubate plate on a plate shaker at any point while running the assay.

KIT CONTENTS & STORAGE

Unopened Kit - ⚗ Store at 2-8°C. Do not use kit past expiration date. Do not re-use the kit.

Part/Description	Storage of opened/reconstituted material
Q-Plex™ Array Microplate Arrayed and blocked 96-well polystyrene microtiter plate	⚗ 2-8°C until kit expiration
Wash Buffer Concentrate (20X) Liquid, 50 mL/vial of a concentrated solution of buffered surfactant	
Sample Diluent (2x) Liquid, 10 mL/vial of a concentrated buffered protein solution with preservatives	
Detection Mix Liquid, 6 mL/vial of biotinylated antibodies in a buffered protein solution with preservatives	
Controls (High, Low, Negative) Lyophilized, human serum diluted in a buffered protein base	⚗ 2-8°C until kit expiration Discard unused reconstituted ckubrator.
Streptavidin-HRP 1X Liquid, 6 mL/vial of streptavidin-conjugated horseradish peroxidase	⚗ ☀ Do not expose to UV light. 2-8°C until kit expiration
Substrate A Liquid, 3 mL/vial of stabilized hydrogen peroxide	⚗ ☀ Do not expose to UV light. Store mixed substrate solution at room temperature (20-25°C) for up to 1 week. Store unmixed solutions at 2-8°C until kit expiration.
Substrate B+ Liquid, 3 mL/vial of stabilized signal enhancer	
Plate Seals (3) Adhesive strips	Non-perishable

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OTHER REQUIRED MATERIALS: INSTRUMENTS AND ACCESSORIES

In addition to the kit contents listed, the following materials are required to run this assay.

1. Multichannel pipette (20-200 µL) and/or a single channel pipette (20-200 µL) and tips

2. Polypropylene tubes or polypropylene 96-well plate(s) for sample and calibrator preparation

    a. Recommended: Nunc® MicroWell™ 96-Well Plates, Polypropylene, 249944; Eppendorf® LoBind Protein or Genomic Microcentrifuge Tubes, 022431102

3. Q-View™ Imager and Software

4. Deionized water

5. Microplate washer (An optional multichannel pipette protocol is provided in Appendix A.)

6. Graduated cylinder for the preparation of wash buffer and storage container

7. 50 mL conical tube or other container for diluting the 2x Sample Diluent

ASSAY PREPARATION

1. Install the Q-View™ Software on the computers that will be used for analysis or operating a Q-View™ Imager Pro or Q-View™ Imager LS.

2. Set up the imager. For imager-specific instructions, see www.quansysbio.com/manuals.

3. Prepare Wash Buffer: Place 50 mL of the 20X concentrate into 950 mL deionized water and mix thoroughly to make 1X Wash Buffer.

4. Prepare Sample Diluent: Dilute the 10 mL of the 2x Sample Diluent into 10 mL of deionized water and mix thoroughly to make 1X Sample Diluent

5. Prepare Controls: Reconstitute using 1X Sample Diluent with the volume on the Product Card which accompanies the kit. Allow Controls to sit for 5 minutes. Mix thoroughly.

6. Allow Substrate A and B+ to come to room temperature (20-25°C). Fifteen minutes prior to use, combine 3 mL of Substrate A with 3 mL of Substrate B+, and mix gently. Do not expose to UV light. Store at room temperature (20-25°C) after mixing.

ASSAY PROCEDURE

Allow all reagents to equilibrate to room temperature (20-25°C) before use and prepare as directed by the previous sections. It is recommended controls be assayed in duplicate.

1. Prepare samples by diluting 1:100 (one part sample to ninety-nine parts prepared sample diluent) with enough 1X Sample Diluent to have 50 µL of diluted sample per well in either polypropylene tubes or a polypropylene 96-well plate.

2. Add 50 µL per well of the each of the controls to duplicate wells of the microarrayed plate.

3. Add 50 µL per well of diluted samples to either single or duplicate wells. Load all samples and controls to the plate within five minutes.

4. Cover the plate with a plate seal provided and **incubate for one hour** at room temperature (20-25°C).

5. Wash the plate three times (see Appendix A).

6. Add 50 µL per well of Detection Mix, cover with a new plate seal, and **incubate for thirty minutes** at room temperature (20-25°C).

7. Wash the plate three times (see Appendix A).

8. Add 50 µL per well of Streptavidin-HRP 1X, cover with a new plate seal, and **incubate for twenty minutes** at room temperature (20-25°C).

9. Wash the plate six times (see Appendix A).

10. Add 50µL per well of previously prepared substrate. Image plate immediately. Wait no longer than 5 minutes to commence imaging.

    Note: If imaging cannot commence immediately, protect the plate from drying for up to 15 minutes by dispensing 100 µL of wash buffer into each well of the plate prior to adding the mixed substrate. When ready to image, remove the wash buffer from the plate and add the substrate.

11. Place the plate in the Q-View™ Imager Pro or Q-View™ Imager LS.

12. Open Q-View™ Software, create or open a project, and click Acquire Image.

13. When using a Q-View™ Imager Pro, set the exposure time to 300 seconds.

14. When using a Q-View™ Imager LS, set the exposure time to 270 seconds.

15. Click the Capture Image(s) button. Users may continue on to Well Assignment while images are being captured.

    Note: Details about these imaging steps are available in the Q-View™ Software Manual viewable at www.quansysbio.com/manuals or within Q-View™ Software under **Support > Manual**.

16. Dispose of all used and unused materials. Disposal of waste may differ from country to country. Please refer to local disposal rules.

ANALYZING A Q-PLEX™ IMAGE

The following summarizes a general workflow for analyzing a Q-Plex™ image in Q-View™ Software. Each of these steps is described in greater detail in the Q-View™ Software and Imager Manual, viewable at www.quansysbio.com/manuals or within Q-View™ Software under **Support > Manual**.

1. Acquire or import an image into Q-View™ Software as described above.

2. Enter the **Product Code** (found on the Product Card) into the **Product Code** field.

3. **Image Processing**: Align the plate overlay as follows:

   a. Set the overlay. If using the **Auto-Set Plate Overlay** feature, this will occur automatically. Otherwise, go to **Overlay Options > Set Plate Overlay.**

   b. To visualize bright or dim spots, optimize the display using **Image Options > Adjust Gamma** (does not affect the data).

   c. Optimize overlay alignment: Go to **Overlay Options > Adjust plate** to pivot the overlay, **Adjust Well** and **Adjust Spot** to move individual wells and spots, then **Auto-Adjust Spots** to automatically snap each circle of the overlay to the nearest spot of the image beneath.

4. **Well Assignment:** Label wells as samples or controls. Use **Templates** to quickly assign layouts that are repeated often or export the layout as a .csv file.

5. **Data Analysis:** Once you have completed Image Processing and Well Assignment, select Data Analysis. Click Perform Analysis to generate charts and statistics. For this qualitative assay, data analysis must be done on signal, which can be viewed on the Report tab and selected from the Statistics menu as "Pixel Intensity".

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6. Interpretation of Results

The assay uses a calculated cutoff value (explained below) to establish the ranges used to determine positive and negative results.

a. **Q-View Software Checks:** Q-View Software provides checks to ensure the validity of the result.

- The Human IgG spot detects human IgG present in a sample. In the case of failure to load an acceptable sample, the Human IgG spot will produce low signal. In this case, Q-View software will report an error code in the Report tab for that sample.

- The software also determines the presence of non-specific well background at several locations within the well. Where non-specific background is present at unacceptable levels, the software will report an error code in the Report tab for that sample.

- The user should review any error codes reported by Q-View software.

b. **Determine the validity of the test:** For a test to be valid, the ratio of the Low Control to the Negative Serum Control must be at least 3 on the S1 assay.

- Average Signal of the Low Control/Average Signal of the Negative Serum Control ≥ 3.

c. **Correct S1 and S2 signal:** For all samples and controls, subtract the within-well Sheep Fc spot signal (spot 3) from SARS-CoV-2 S1 (spot 1) and SARS-CoV-2 S2 (spot 2) to create the corrected S1 and S2 signals. If the result is <0, replace result with 0.

d. Calculate the average corrected High Control S1 and S2 signal.

e. Calculate the average corrected Low Control S1 and S2 signal.

f. **Determine the S1 and S2 Cutoff Values:** Calculate the Control Ratios for S1 and S2 by dividing their respective average corrected Low Control signal by their average corrected High Control signal.

g. Multiply the Control Ratio by the Lot Cutoff Correction Value on the Product Card. These adjusted values are the Cutoff Values for the S1 and S2 assays.

h. **Determine the S1 and S2 sample specific ratios:** Calculate the S1 and S2 Sample Ratio of each sample by dividing corrected sample value (step 6.c.) by the average corrected High Control (step 6.d.) and compare to the S1 and S2 Cutoff Values (step 6.g.). Samples with ratios on S1 that are higher than the S1 cutoff are positive for the presence of IgGs to the Spike 1 protein. Samples with ratios on S2 that are higher than the S2 cutoff are positive for the presence of IgGs to the Spike 2 protein.

7. Data Interpretation Example:

Sample		S1 Signal	S2 Signal	Sheep Fc Signal
High Control	Replicate 1	49182	50307	1480
	Replicate 2	48320	49799	1288
Low Control	Replicate 1	3684	14893	467
	Replicate 2	3540	14309	449
Negative Serum Control	Replicate 1	279	1312	1586
	Replicate 2	269	1260	1524
Sample A	Single replicate	302	780	1025
Sample B	Single Replicate	15704	6151	1282

Determine the validity of the test:

- Average Signal of the Low Control / Average Signal of the Negative Serum Control = (3612/274) = 13.1 ≥ 3. The test is valid.

Correct S1 and S2 signal: Subtract within well Sheep Fc signal to calculate corrected S1 and S2 signal.

- Example: S1 High Control Replicate 1 (49182) – Fc High Control (1480) = 47702

Sample		Corrected S1 Signal	Corrected S2 Signal
High Control	Replicate 1	47702	48827
	Replicate 2	47032	48511
Low Control	Replicate 1	3217	14426
	Replicate 2	3091	13860
Negative Serum Control	Replicate 1	0	0
	Replicate 2	0	0
Sample A	Single replicate	0	0
Sample B	Single replicate	14422	4869

Calculate the average of all replicate data

Sample	Average Corrected S1 Signal	Average Corrected S2 Signal
High Control	47367	48669
Low Control	3154	14142
Negative Serum Control	0	0
Sample A	0	0
Sample B	14422	4869

Determine the S1 and S2 Cutoff Values:

- Ratio of the Low Control to the High Control for S1 = 3154/47367 = 0.067

- Ratio of the Low Control to the High Control for S2 = 14143/48669 = 0.29

- Multiply the ratio of the Low Control to the High Control by the Lot Correction Factor: 0.067 * 0.75 = 0.050. This is the cutoff for the S1 assay.

- Multiply the ratio of the Low Control to the High Control by the Lot Correction Factor: 0.29 * 0.41 = 0.12. This is the cutoff for the S2 assay.

Determine the S1 and S2 sample specific ratios:

	S1 Sample Specific Ratio	S2 Sample Specific Ratio
Sample A	0	0
Sample B	0.30	0.10

- Sample A is negative on the S1 assay: 0 < 0.050.

- Sample A is negative on the S2 assay: 0 < 0.12.

- Sample B is positive on the S1 assay: 0.30 > 0.050.

- Sample B is negative on the S2 assay: 0.10 < 0.12.

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Tips for data analysis are available at www.quansysbio.com/tech-tips. We take great care to ensure that customers have success using our products and services. If you have further questions about running the assay, data analysis, troubleshooting, or our products or services, please contact us at 888-QUANSYS (782-6797) or at support@quansysbio.com.

APPENDIX A: PLATE WASHING METHOD

1. Use a program that will aspirate and dispense 300-400 µL wash buffer.

Aspirate ➡️ **Dispense**
300 - 400 µL
Wash Buffer

3 to 6 Times

Aspirate

2. Ensure that the plate washer has a program that will not scratch the bottom of the microplate and will prevent plate drying. This is critical to prevent damage to the capture antibody arrays. The simplest method to avoid plate drying is to leave a small, uniform amount (1-3 µL) of wash in the well after the final aspiration, and add the next reagent to the plate as quickly as possible.

3. Leaving a uniform amount of wash in the wells can be accomplished with an automated washer by slightly increasing the aspiration height of the washer head.

   For example:

Process	Distance	Steps on a Biotek ELX-405
Aspiration Height	3.81 mm	30
Aspiration Position	1.28 mm from center	-28
Dispense Height	15.24 mm	120
No soak or shake cycles are needed		

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4. Connect the prepared wash buffer to your automatic plate washer.

5. Run 1-2 priming cycles to make sure that the wash buffer is running through the plate washer. When the buffer has run through the machine, the waste will be foamy.

6. In a spare microtiter plate, dispense 100 ul wash buffer, ensure that all pins dispense uniformly, then aspirate and ensure that all pins aspirate uniformly. This will ensure that all pins are functioning.

7. Prime the plate washer one time before the first wash step. When running the assay, perform the wash 3 or 6 times according to the protocol.

Multichannel Pipette Wash Method

1. Just prior to washing, pour the prepared wash buffer into a trough or tray.

2. After each incubation, flick the solution out of the plate over a waste container before starting the wash protocol.

3. Using a multichannel pipette, dispense 400 µL of wash buffer into each of the wells used in the test.

4. Aggressively flick the wash buffer out over a waste container.

5. This washes the plate one time. When the assay procedure calls for three or six washes, repeat steps 3-4 accordingly.

6. Tap the plate upside down on a paper towel to remove any residual wash.

7. Proceed immediately to dispense the next solution so drying does not occur.
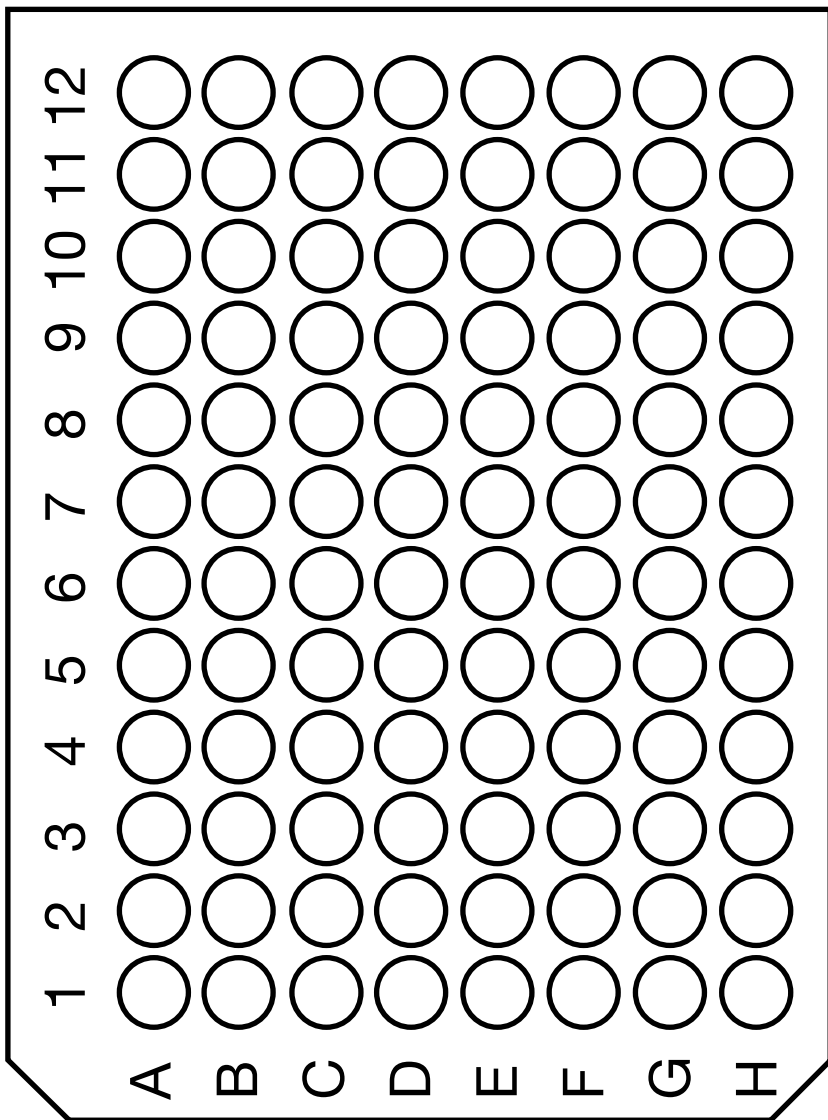
ABBREVIATED PROTOCOL

Preparation

1. Install Q-View™ Software *(page 8)*.

2. Set up the imager *(page 8)*.

3. Set up microplate washer *(page 16)*.

4. Reconstitute and prepare reagents *(page 8).*

Running the Assay

5. Prepare the controls by reconstituting with Sample Diluent according to the Product Card *(page 8)*.

6. Prepare the samples with Sample Diluent *(page 8)*.

7. Load the controls and samples onto the plate. Incubate for one hour at room temperature *(page 8)*.

8. Wash the plate three times, add the Detection Mix, and incubate for thirty minutes at room temperature *(page 9)*.

9. Wash the plate three times, add the Streptavidin HRP 1X, incubate for twenty minutes at room temperature *(page 9)*.

10. Allow Substrate A and Substrate B+ to come to room temperature, then mix equal volumes and allow the solution to sit at room temperature *(page 8)*.

11. Wash the plate six times and add the mixed Substrate *(page 9)*.

12. Capture and analyze image of the plate *(page 9)*.

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PLATE DIAGRAM

NOTES

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