



innovation for health & wellness

DECLARATION OF CONFORMITY

We Matriks Biotechnology Co.
Gazi Universitesi,
Golbasi yerleskesi,
C blok Zemin kat no:10/50c-47
06830 Ankara
Turkey

herewith declare under our own responsibility, that the product

CORONAHUNTER™ Q-CORS_{RBD} Anti-SARS-CoV-2 SPIKE RBD IgM ELISA (COR-QNS-IGM-SRBD)

and the following components:

Microtiter Plate	1 x 12 x 8	Microtiter plate Break apart strips. Microtiter plate with 12 rows each of 8 wells coated with reactant.
Standard A-E	0,2 mL (each)	Standards A-E Standard A: 100 ng/mL Standard B: 50 ng/mL Standard C: 25 ng/mL Standard D: 12,5 ng/mL Standard E: 0 ng/mL Ready to use. Used for the standard curve and control. Contains SPIKE RBD IgM antibody, human serum and stabilizer, <0,1 % NaN ₃
Controls	0,2 mL (each)	Control low and high levels Ready to use. Contains human serum and stabilizer, <0,1 % NaN ₃ Control concentrations are given in "Quality control certificate"
Assay Buffer	1 x 50 mL	Assay buffer Ready to use. Blue coloured. Contains proteins, <0,1 % NaN ₃
Conjugate	1 x 12 mL	Horse radish peroxidase conjugated probe Ready to use. Red coloured. Contains HRP conjugated probe, stabilizer and preservatives.
Substrate	1 x 12 mL	TMB substrate solution Ready to use. Contains 3,3',5,5'- Tetramethylbenzidine (TMB)
Stop Buffer	1 x 12 mL	TMB stop solution Ready to use. 1N HCl
Wash Buffer	1 x 50 mL	Wash buffer (20x) Prepared concentrated (20x) and should be diluted with the dilution rate given in the "Pre-test setup instructions" before the test. Contains buffer with tween 20.
Foil	2 x 1	Adhesive Foil For covering microtiter plate during incubation

is in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct. 27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures in

Annex 111 (2-5)

Issue date: 2021-02-17

Olgu Örs Başak

Quality Management Representative

The conformity of the above mentioned product is checked at least every 3 years. This is documented by rechecking and signing the essential requirements.