Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Langen, 11 July 2022

Information for Manufacturers and Distributors

COVID-19 ANTIGEN TESTS

In response to the numerous inquiries received, the Paul-Ehrlich-Institut would like to provide information on the current distribution of responsibilities regarding the evaluation of rapid antigen tests for professional use.

The "Third Ordinance amending the Coronavirus Testing Ordinance on 29 June 2022" was published by the Federal Ministry of Health in the Federal Gazette. It became valid on 30 June 2022 (text in German only):

www.bundesanzeiger.de/pub/publication/oLkvcL7aBEpNfC03aH7/content/oLkvcL7aBEpNfC03aH7/BAnz%20AT%2029.06.2022%20V1.pdf

The amendment to the Coronavirus Testing Ordinance introduced new regulations for the reimbursement of rapid antigen tests. The right to testing pursuant to section 1 sentence 1 of the Coronavirus Testing Ordinance is limited to those POC rapid antigen tests (point of care antigen tests, here: rapid antigen tests for professional use) which have been or will be included in the "EU Common List of COVID-19 Rapid Antigen Tests" adopted by the Health Security Committee of the European Union (EU). This list, which also contains information on the criteria for inclusion in the list, is now available on the EU's website.

https://health.ec.europa.eu/health-security-and-infectious-diseases/crisis-management/covid-19-diagnostic-tests_en#common-list-of-corona-antigen-rapid-tests

In the future, the only POC rapid antigen tests that are reimbursable at the expense of the statutory health insurance system (Gesetzliche Krankenversicherung, GKV) will be those tests that have been included in the EU list.

The market overview (BfArM list) previously compiled by the Federal Institute for Drugs and Medical Devices (BfArM), which listed the antigen tests that met the minimum criteria of the Paul-Ehrlich-Institut and Robert Koch-Institut (RKI), was discontinued due to the new regulation. The table "Comparative Evaluation of the Sensitivity of SARS-CoV-2 Rapid Antigen Tests" on the Paul-Ehrlich-Institut's website was also discontinued. This table includes lists of both the antigen tests for professional use and the antigen tests for self-use.

From now on, only a CE marking is required in order to place rapid antigen tests for self-use on the market.

All requests or inquiries regarding the listing of POC rapid antigen tests must therefore be submitted to the Technical Working Group on COVID-19 Diagnostic Tests of the EU Health Security Committee.

If you have any questions about the Technical Working Group on COVID-19 Diagnostic Tests application procedures, please contact:

SANTE-TWG-RAT@ec.europa.eu

For technical questions regarding the COVID-19 database for in vitro diagnostic medical devices and for information provided by manufacturers, please contact:

JRC-COVID-DIAGNOSTICS@ec.europa.eu

Further information

www.pei.de/EN/newsroom/hp-news/2022/220705-rapid-antigen-tests-detection-coronavirus-reimbursable-gkv.html