The SARS-CoV-2 Omicron variant emerged between 2021 and 2022, replacing the Delta variant. The new mutation produced a reduction in the duration of symptoms, in the risk of hospitalization and in the incubation time, but a greater contagiousness. This underlined the need in hospital settings for a rapid screening through specific and sensitive methods for the new variant.

**AIM AND OBJECTIVES**

The Hospital Pharmacy, in collaboration with the Virology Department, participated at the evaluation of a variety of diagnostic devices, aiming at the acquisition of a rapid antigen test.

**BACKGROUND AND IMPORTANCE**

**MATERIAL AND METHODS**

The Hospital Pharmacy collected technical documentation of 15 rapid antigen tests, based on the in vitro immunochromatographic technique for the qualitative detection of the nucleocapsid protein antigen from Sars-Cov-2, on salivary and nasopharyngeal / oropharyngeal samples.

According to datasheets, IFU and CE certificates, we evaluated:
- coherence of sample collection methods with national guidelines;
- ease of execution of the test and interpretation of the results;
- validity of CE certificates;
- registration of the devices on the national medical device database.

Virologists simultaneously studied specificity, CT20 sensitivity, CT24 sensitivity of the tests.

**RESULTS**

According to virological analyzes, 1 test was rejected because the salivary matrix was found to be invalid for the detection of the Omicron variant, 5 were excluded due to poor sensitivity. From the comparison of the registration numbers of these devices, it emerged that 3 of them were presented twice as they were marketed under different names. From the IFU and CE certificates analysis, 3 tests were authorized by the certification bodies only for self-diagnostic and non-professional use and therefore excluded. For 1 test the reagent included in the kit was multidose, therefore not suitable for management in the ward. Lastly, the choice of the acquisition between the last 2 tests was based on economic evaluations and ready availability on the market.

**CONCLUSION AND RELEVANCE**

The collaboration between Hospital Pharmacy and Virology resulted in sharing specific knowledge and skills. Consequently, the selection of rapid antigen tests for the Omicron variant was possible thanks to a multidisciplinary process, in compliance with the criteria provided by the Ministerial Guidelines and the new 2017/745 European Regulation.