**Minimum Requirements of tender SANTE/2020/C3/082 for the supply of antigen tests for diagnostic of COVID-19**

| Type | Minimum requirements | | |
|---|---|---|---|
| | Description/Features | EU legislation | Reference standards / Technical advice (not-obligatory) |
| Rapid antigen test kit (visual read) | • All-in-one test kit (including swabs), for use at point of care (preference) or in laboratory settings<br>• Control line<br>• Test result via visual read, not requiring a test reader instrument<br>• *In vitro* performance declared by the company:<br>- Sensitivity: high (above 90%) compared to RT-PCR<br>- Specificity: high (above 97%) compared to RT-PCR<br>• Specification of intended testing in at least two different settings and target populations<br>• Details of specimen collection requirements<br>• Results within 30 minutes<br>• Shelf-life minimum of 6-months, preferably longer<br>• Use at room temperature<br>• WHO recommendation[1]<br>• | • Directive 98/79/EC on *in vitro* diagnostic medical devices[2]<br>• CE–marked, EC or EU declaration of conformity<br>• Directive 93/42/EEC on medical devices[3]<br>• Regulation (EU) 2017/745 on Medical Devices[4]<br>• Regulation (EU) 2017/746 on in vitro diagnostic medical devices[5]<br>•<br>• | • Relevant harmonised European standards[6] (e.g. EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices)<br>• Other relevant requirements<br>• FDA emergency authorisation<br>• FINDdx[7] evaluated |

[1] WHO Emergency Use Listing for In vitro diagnostics (IVDs) Detecting SARS-CoV-2, version 02/10/2020, https://www.who.int/diagnostics_laboratory/201002_eul_sars_cov2_product_list.pdf?ua=1

[2] OJ L 331, 7.12.1998, p. 1. https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en

[3] OJ L 169, 12.7.1993, p. 1.

[4] OJ L 117, 5.5.2017, p. 1.

[5] OJ L 117, 5.5.2017, p. 176.

[6] References to harmonised European standards conferring presumption of conformity with the requirements of Directive 93/42/EEC on medical devices and of Directive 98/79/EC on *in vitro* diagnostic medical devices are published in the *Official Journal of the European Union* (OJ L 90I, 25.3.2020). See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2020:090I:TOC.

[7] As recommended by FINDdx on https://www.finddx.org/covid-19/sarscov2-eval-antigen/.