



Application Note



Pharmaceutical Coding on diagnostic test kits

Diagnostic tests are playing an essential role for a rapid and effective response to global medical crises and diseases as they contribute to patient screening, diagnosis, and monitoring. They are classified as medical devices and are subjected to local regulations such as the US Unique Device Identification (UDI) system, or the European Medical Device Regulation (MDR), and must be labeled accordingly. Videojet can help manufacturers and packagers comply with these legal requirements by offering innovative coding solutions for all components of diagnostic test kits.

Coding requirements

COVID diagnostic tests are considered as in-vitro diagnostics, as they are tests done on samples such as blood or tissue that have been taken from the human body to detect diseases or other conditions, as well as monitor a person's overall health to help cure, treat, or prevent diseases.

In-vitro diagnostic tests used for COVID-19 can be classified into two groups. The first group contains PCR (polymerase chain reaction) and rapid antigen tests, that can detect the presence of the virus itself. The main purposes of these tests are to support the diagnosis of patients with symptoms, to screen for infections, and to test whether an individual who has recovered from COVID is still infectious. The second group of tests detect the presence of antibodies against the virus in the human body (antibody test). Testing for these antibodies can tell whether a person was previously infected and provide information about possible protection against new infections.

Samples needed for antigen tests are typically collected with a nasal or throat swab, or saliva collected by spitting into a tube. For antibody tests, blood is collected from the fingertip using a capillary tube. While PCR tests need to be done by a medical professional and evaluated in a laboratory, rapid antigen and rapid antibody tests can be performed completely autonomously at home. These rapid test kits usually include:

- a test cassette, that is packed into an air and dust tight pouch to help ensure that the test cassette is not compromised before use, along with a desiccant pack
- a nasal or throat swab in sterile packaging
- processing tubes containing liquid reagent

According to the European Medical Device Regulation and US FDA 21 CFR, each medical device must be accompanied by the information necessary to identify the device and its manufacturer. This information may appear on the product itself or, if this is not possible, on the packaging. Typical requirements are:

- Name or trade name of the device
- Name, registered trade name, or registered trade mark of the manufacturer
- Lot number or batch number
- Date of manufacture
- Expiration date

Coding solutions for diagnostic test kits

Test Cassette

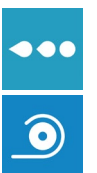
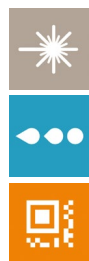
Test cassettes are marked with letters showing the control bar and the test result, as well as the type of the test. Additionally, they can be marked with a QR code so that, once the test is performed, the code can be scanned and the information sent to a central health organization.

Since test cassettes are made of plastic materials, fiber laser marking systems, continuous inkjet (CIJ) printers, and thermal inkjet (TIJ) printers are ideal solutions for coding directly onto the test cassette. Fiber laser marking machines operate by delivering a wavelength of 1.064 micrometers and apply high-contrast, permanent marks on hard plastics and metals. With marking speeds up to 2,000 characters per second, Videojet fiber lasers are an ideal solution for demanding production schedules in the pharmaceutical industry.

Pouch

Thermal transfer overprinters (TTO) and continuous inkjet printers are most suitable for coding onto pouches that provide the necessary protection from light and moisture to help ensure that the test cassettes are not compromised before they are used.

CIJ printers from Videojet are ideal for printing up to five lines of text, linear and 2D bar codes, or graphics on flat or curved surfaces, even at high speeds and in continuous production environments. A wide range of CIJ inks are available to adhere to virtually any substrate in any shape. For coding onto pouches, Videojet recommends using our V4234 ink, as it is very robust and has good splash, soak, and rub resistance.





Label

Labels of the processing tubes containing liquid reagent also need to include appropriate storage instructions adequate to protect the stability of the product and a declaration that the device is in a sterile condition. CO₂ laser marking systems, TIJ, and TTO systems are most suitable for coding onto labels.

TTO is an ideal technology for printing high-resolution, variable-content codes on thin, flexible packaging such as films, pouches, and labels. High speed TTO systems from Videojet are available in two widths, 53mm and an industry first airless 107mm. For printing onto pouches and labels, Videojet recommends using our Super Standard Ribbons. For excellent sensitivity and compatibility with rough substrates such as medical grade paper and DuPont™ Tyvek®, Videojet recommends our Rough Texture Ribbons.



Swab Packaging

To help ensure that the device is sterile until the point of use and having a barrier to microbial penetration, nasal or throat swabs are sterile packed in medical grade paper or DuPont™ Tyvek®. CIJ, TTO, and TIJ printers are ideal solutions for coding onto this type of packaging.

TIJ printers from Videojet Wolke use a non-contact printing technology that enables high-speed, high-resolution printing up to 600 dpi on flat and slightly uneven surfaces. A TIJ controller can drive up to 4 printheads (0.5" / 12.7mm) independently or together and deliver breakthrough integration versatility with clean, no-mess operation. For printing onto medical grade paper and DuPont™ Tyvek®, Videojet recommends using Wolke Global Solvent Ink. It is manufactured in-house by industry leading ink experts and offers proven performance that rivals other solvent-based inks.

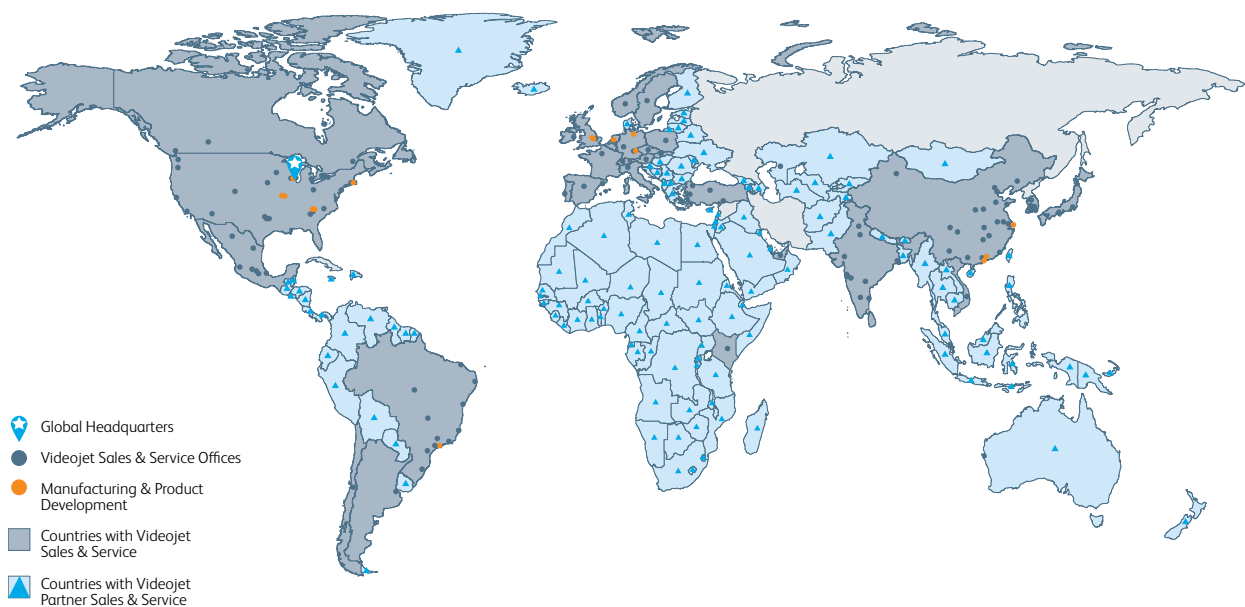


Peace of mind comes as standard

Videojet Technologies is a world leader in industrial coding and marking solutions with a dedicated global healthcare team supporting organizations and supply chain partners with solutions, certifications and fast, reliable service.

A product portfolio including thermal inkjet, laser marking, continuous inkjet and labeling provides consistent, high-quality serialization and traceability codes, helping the pharmaceutical and medical device industries safeguard their products against counterfeiting and protect consumer safety. With a wide range of technologies addressing virtually any application, Videojet is the expert in realizing the specific requirements of a wide range of healthcare applications.

With decades of knowledge, Videojet Technologies' expertise in industry standards and global regulations makes them the right partner for understanding complex coding needs. Videojet solutions code 10 billion products a day worldwide, playing a vital and responsible role in the world. With over 4,000 associates serving 135 countries, Videojet has the capability to provide local service through global resources.



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This Application Note is for informational purposes only, and is not intended to provide legal advice. Please consult with your counsel about your specific requirements for the identification of medical devices in commerce.