



attana

life science and diagnostics

Attana has obtained CE-IVD Marking for its first products within clinical diagnostics

Attana has today registered the AVA™ SARS-CoV-2 IgG Immunoassay and the analytical instrument Attana Cell™ 250 for CE-IVD Marking with the Swedish Medical Products Agency ("Läkemedelsverket"). The test and the instrument meet all applicable requirements for CE-IVD Marking, which allows Attana to start marketing and selling the products to clinical laboratories within the EU.

Attana's CE-IVD Marked products

The CE-IVD Marked test is a serological immunoassay for the detection of SARS-CoV-2 IgG antibodies and is used with Attana's analytical instruments. The CE-IVD Marking initially includes both a qualitative and semi-quantitative measurement of IgG antibodies in serum. Laboratories that use Attana's diagnostic platform will for research purposes also have access to unique data, such as non-specific immune response, quality of specific antibodies, and concentration of IgA and IgM antibodies.

About the studies behind the CE-IVD Marking

The technical studies behind the CE-IVD Marking have been performed in Kalmar, Sweden in collaboration with the Linnaeus University and Region Kalmar. The studies include blood samples from 110 individuals, of which 52 had SARS-CoV-2 IgG antibodies, confirmed by independent ELISA tests. All serum samples were analyzed with Attana's CE-IVD Marked kits and compared with results from two ELISA-based tests. In addition, Attana has performed studies ensuring linearity, precision, reproducibility and other performance measurements in accordance with the relevant CE-IVD requirements. These studies have all shown very good results and will be presented in one or more scientific publications that are being prepared together with the Linnaeus University and Region Kalmar.

The attached picture shows the input and output of the immunoassay divided between what is CE-IVD Marked and what can be used for research purposes.

Comparing Attana's method with ELISA

The major difference in Attana's method is that Attana immunoassays are performed in real time whereas other certified SARS-CoV-2 immunoassays are based on blood samples being incubated for several minutes prior to measurement. Attana's real-time analysis thus better mimics the conditions within the human body (*in vivo*) and accordingly likely provides more biologically relevant diagnostic data. Despite this methodological difference, Attana's SARS-CoV-2 IgG immunoassay shows similar sensitivity and specificity compared to the two ELISA methods as they do when compared to each other.

Continued regulatory process

In addition to serum, Attana's test also allows for analysis of both whole blood (capillary fingerprick) and plasma, for research use. Attana will continuously update the CE-IVD Marking to also include these blood sample types. The ambition is to also seek regulatory approval for a quality assessment of SARS-CoV-2 IgG antibodies based on Attana's instruments and test kits.

Teodor Aastrup, CEO of Attana, comments:

"This CE-IVD Marking, confirms that Attana's technical platform is as relevant for advanced diagnostics as it is for drug development. Our collaboration with Linnaeus University and Region Kalmar has already resulted in very interesting data, some of which form the basis for this CE-IVD Marking. During the summer and autumn, we will continue to perform a large number of analyses to, among other things, look at the effect of different vaccines and immune responses against different SARS-CoV-2 variants. In the coming months, we also look forward to further commercializing our offering together with our distribution partners ensuring a successful market introduction of our diagnostic products."

For more information, please contact:

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The Board of directors for Attana consider that the information in this press release is not likely to have a significant effect on the share price but is of general interest for the shareholders and hence should be communicated.

About Attana

Attana was founded in 2002 with the vision of *in vitro* characterization of molecular interactions mimicking *in vivo* conditions. Since then, Attana has developed proprietary label free biosensors for biochemical, crude, sera, and cell-based assays and the Attana Virus Analytics (AVA) platform, a proprietary *in vitro* diagnostics (IVD) tool. Attana products and research services are used by Big Pharma, biotech companies and academic institutions within the life sciences. To learn more about our latest services and products, please visit www.attana.com or contact sales@attana.com