



Uppsala 15 April 2019

PRESS RELEASE

## **AroCell and Corgenix establish the measurement of Thymidine Kinase 1 using AroCell TK 210 ELISA in a CLIA-lab in the USA**

**AroCell AB (AROC NASDAQ Stockholm) announce today, in collaboration with Corgenix (Corgenix Inc., Colorado USA) that the AroCell TK 210 ELISA kit has been validated and approved for Thymidine Kinase 1 (TK1) measurements in human samples for preclinical and clinical use at the Corgenix laboratory facility in Colorado, USA.**

This collaboration will make AroCell's patented biomarker assay available both as a service and as in the already existing AroCell TK 210 ELISA kit for measurements of TK1 protein concentrations in human serum samples. This will provide maximum flexibility for our customers in the USA. It also extends the services that Corgenix offers in their CAP compliant CLIA-lab (Clinical Laboratory Improvement Amendments-lab).

Corgenix has over 25 years of experience in the *In Vitro* Diagnostic (IVD) industry focused on product development, manufacturing, regulation, distribution and contract services with a CAP/CLIA-lab based in Colorado, USA. A CAP/CLIA-lab is a clinical laboratory for human sample testing that follow CAP standards in USA. The AroCell TK 210 ELISA assay validation has been successfully completed and added to Corgenix laboratory test menu.

"The Corgenix Clinical Laboratory offers clients a regulated environment to understand unique biomarkers in their sample sets" says Kelly R Pitts, Ph.D., General Manager and Chief Scientific Officer at Corgenix. "Adding the AroCell TK1 assay to our menu further expands our ability to serve clients that are extending the boundaries of therapeutic approaches in oncology and beyond."

"We are excited about this opportunity to collaborate with Corgenix by providing the service of measuring TK1 protein using AroCell's TK 210 ELISA in their laboratory. This will strengthen our position in the U.S. and is in line with AroCell's commercialization strategy to make AroCell TK 210 ELISA widely available. It will facilitate the use of TK1 measurements in clinical research as well as for drug development within the pharmaceutical industry" says Michael Brobjer, CEO of AroCell. "The successful validation of our kit into Corgenix facility also proves the robustness and easy handling of the kit."

Thymidine Kinase 1 is a valuable tumor biomarker and the availability of a TK1 protein assays in a CLIA registered laboratory in the USA will make its application easier and more convenient for the pharmaceutical industry and clinical research.

AroCell TK 210 ELISA is the only available test to measure TK1 protein concentrations in serum blood and is CE marked in EU/ESS.

**For more information:**

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*AroCell is obliged to make public this information pursuant to the EU Market Abuse Regulation. This information was submitted for publication through the agency of Michael Brobjer, April 15, 2019 at 08:00.*

### **About Thymidine Kinase 1**

Thymidine Kinase 1 (TK1) is a key enzyme in DNA precursor synthesis. It is upregulated during the late G1 phase and early S phase of the cell cycle and its presence in cells is an indicator of active cell proliferation. Increased levels of TK1 in the blood can indicate active cell proliferation as a consequence of abnormal cell turnover and cell disruption triggered by for example therapeutic agents.

### **About CLIA Labs**

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 260,000 laboratory entities. The Division of Clinical Laboratory Improvement & Quality, within the Quality, Safety & Oversight Group, under the Center for Clinical Standards and Quality (CCSQ) has the responsibility for implementing the CLIA Program. The objective of the CLIA program is to ensure quality laboratory testing. Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities.

### **About Corgenix**

Corgenix, Inc. is a US-based company focused on *In Vitro* Diagnostic (IVD) development, manufacturing, and commercialization in the companion and complementary diagnostic space. With its CAP/CLIA laboratory (Corgenix Clinical Laboratory), it partners with diagnostic, pharmaceutical, biotechnology, device, and academic organizations to provide unique testing that facilitates discovery, development, clinical, and regulatory strategies leading to successful outcomes for its clients. For more information, [www.corgenix.com](http://www.corgenix.com)

### **About AroCell**

AroCell AB (AROC) is a Swedish company that develops standardized modern blood tests to support the prognosis and follow up of cancer patients. AroCell's new technology is based on patented methods to measure Thymidine Kinase 1 (TK1) protein concentrations in a blood sample. The TK 210 ELISA test provides valuable information mainly about the condition of cancer patients. This may help clinicians to optimize treatment strategies and estimate the risk of recurrence of tumor disease during monitoring of the disease. AroCell (AROC) is listed at Nasdaq First North with Redeye AB as Certified Adviser: [Certifiedadviser@redeye.se](mailto:Certifiedadviser@redeye.se), +46 (0)8 121 576 90. For more information; [www.arocell.com](http://www.arocell.com)