Qanta scope

iVV ASSAY

...BECAUSE YOUR PATIENT IS WORTH IT...

LEUKEMIA

Treating leukemia and other hematological malignancies can be challenging mainly because of the diversity of the disease. iVV assay™ is a perfect solution for the patient group which fails to be cured by the first line therapies.

ADVANCED CANCER

Occasionally solid tumors can give incident of production of ascitic fluids or pleural effusions full of tumor cells. Using body cavity fluids containing tumor cells with iVV assay can further explore treatment options.

PATIENT SELECTION

Patients who have exhausted treatment options can still be further examined with iVV assay to find a possible successful therapy.
Clinical trials can also be assisted with the assay to increase hit rate.

CE IVD

use

Personalized Cancer Diagnostics

iVV ASSAY

ASSISTING PERSONALIZED ONCOTHERAPY

iVV assay™ in combination with HexascopeHAEMA™ automated scanner and image analyzer platform is a three day diagnostic drug sensitivity laboratory test. It is a new technology where tumor cells are extracted from the freshly taken patient sample, originating from blood, bone-marrow, ascitic fluid or pleural effusion. The tumor cells are than incubated with different medications and survival is monitored to find the most effective therapy.

QantaScope is a Swedish company introducing new methods and patented technologies for routine cancer diagnostics in patient preselection.

Cancer is a difficult disease to treat with constant challenges. This disorder changes over time and even within the same patient. Modern science revealed why cancer can evolve and escape even the most promising therapies. The reason lies in the very large number of genetic errors accumulating in every cancer cell. Today we know that thousands of mutations make every cancer unique and a unique cancer requires an individualized treatment.

To achieve that, iVV assay™ has been developed at Karolinska Institute in Sweden, to assist the clinician in the choice of cancer therapy. The tumor cells are isolated directly from the patient's blood, bone-marrow or body fluids and incubated under unique conditions in a patented cell culture medium which keeps the cells less sensitive to environmental stress and better keep their original properties.

Assay guided therapy gives a chance even for advanced cancer patients who already exhausted the standard treatment options. iVV assay™ may protect from the adverse effects of unjustified chemotherapy agents and prolong life by finding the few remaining effective medications. iVV assay™ may also increase the success rate in clinical trials by preselecting patients attending the clinical study in Phase II or Phase III. It can also be the right choice for new drugs trying to enter into the clinical market by serving as a perfect diagnostic tool.

iVV assay™ platform includes different types of reagent kits with different substance composition and HexascopeHAEMA™ an automated scanner and image analyzer. The system has been adapted to the routine diagnostic laboratory workflow.

Unique tumor-Unique treatment

iVV assay™ is the only CE IVD certified tool today which creates an opportunity to examine the patients' living tumor cells outside of the human body and monitor their survival for each administered drug to ease the understanding of their drug sensitivity profile.

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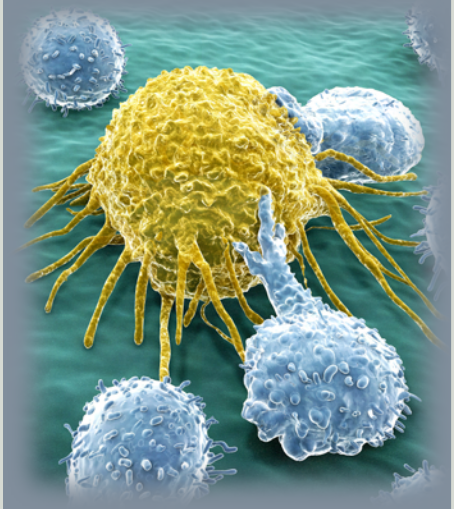
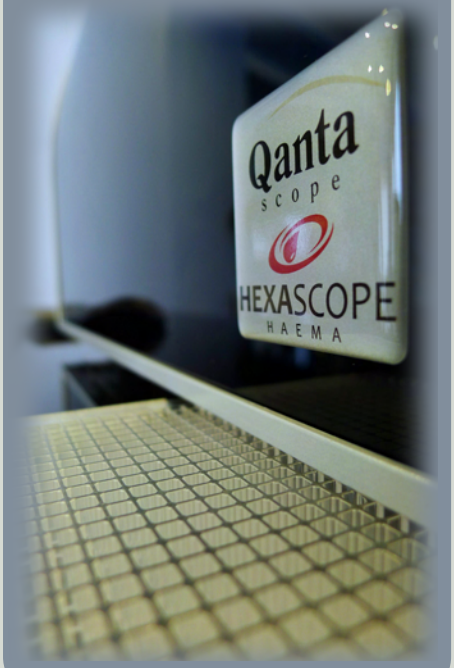
THE ASSAY





The In Vitro Viability Assay "iVV assay™"

The iVV assay™ can be adjusted to different needs and different treatment protocols. It offers a broad diversity of medications which can be adapted for every country and all treatment habits. The assay uses a patented cell incubation medium (OmniSanguine), which mimics the in vivo environment of the tumor cells. This step is the most important in order to avoid or at least minimize all in vitro environmental stress that tumor cells usually encounter while being outside of the human body. The major problem with stressed cells is that they become weaker, less viable and more sensitive to all kinds of treatment in the laboratory. Oversensitivity would cause false positive results for the different substances which would make the adaptation of the treatment recommendation fail in clinics. iVV assay™ systematically solved most of the problems that laboratories were facing during the work with fresh primary tumor cells. The iVV assay™ requires a device to measure and analyze tumor cell viability. QantaScope HexascopeHAEMA™ is an automated scanner and image analyzer which monitors the survival of the fluorescent labelled tumor cells on a 384-well drug coated plate after 3 days of incubation at 37°C.

The test protocol and report

Primary tumor cells are extracted from the patient sample. The tumor cells are incubated over a 72 hour period with 30 different medications at 37°C in a CO_2 incubator. Every drug is tested in four different concentrations in three measurements (triplicates) controlled by a barcode system. The tumor cells are labelled with VitalDye, which labels the live and dead cells differently. The 384-well drug plate with the fluorescent labelled cells are analyzed with HexascopeHAEMA™ instrument, creating a digital report file, where the 30 different substances are ranked according to their tumor cell killing efficiency (KE%) and a clinical report where the drug sensitivity status of the patient is demonstrated. The number of tumor cells is calculated using advanced algorithms and statistical calculations. The software makes a very robust analysis, where even smaller cell clumps or different morphological appearances can be visualized and analyzed. The report is aimed to be sent to the oncologist or hematologist who makes the final treatment decision in accordance with the patient's general health status, diagnosis and other diagnostic parameters.

Limitations of the test

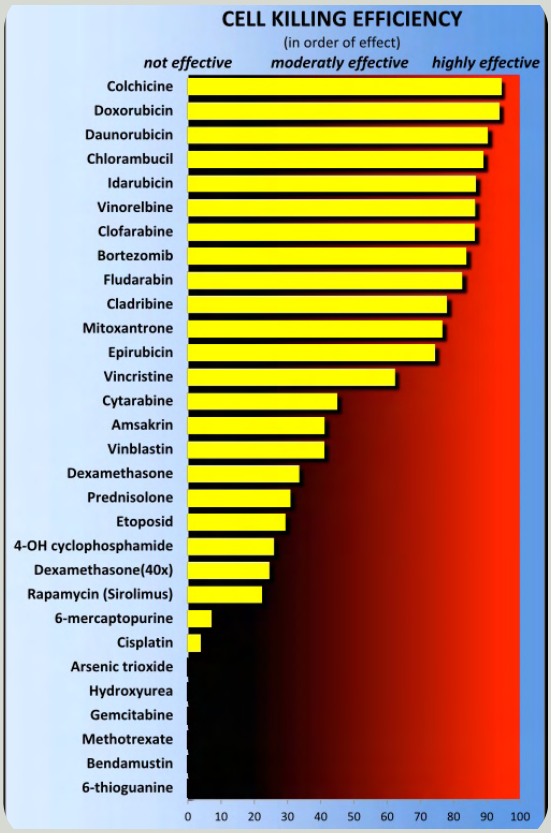
Protein based medications can not be tested and substances, -which need to be activated in the body,- have limited access.

iVV assay for future cancer care

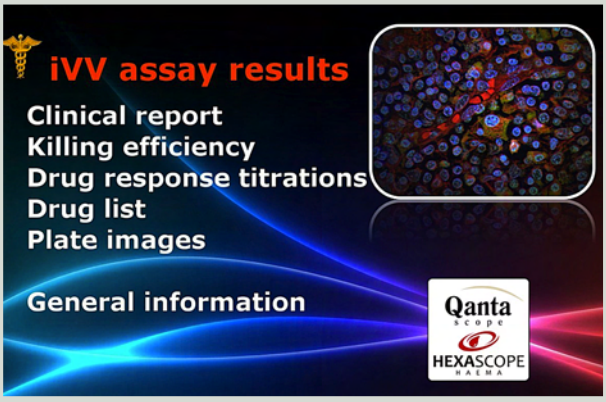
THE RESULT REPORT FILES

The iVV assay™ workflow

The clinical result file

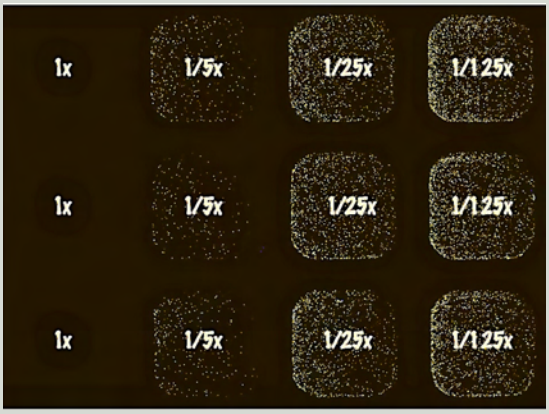


The killing efficiency (KE%) file

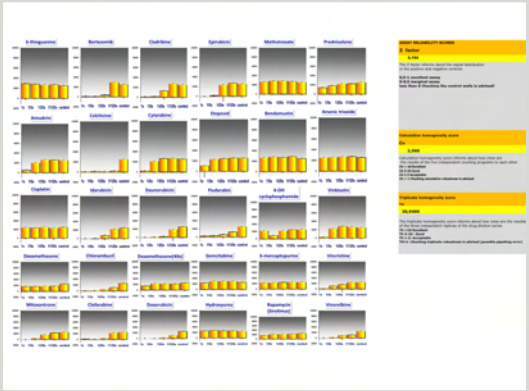


The main report page

The 384-well drug plate setup



The 4 different concentration in triplicates for each drug



The titration curves

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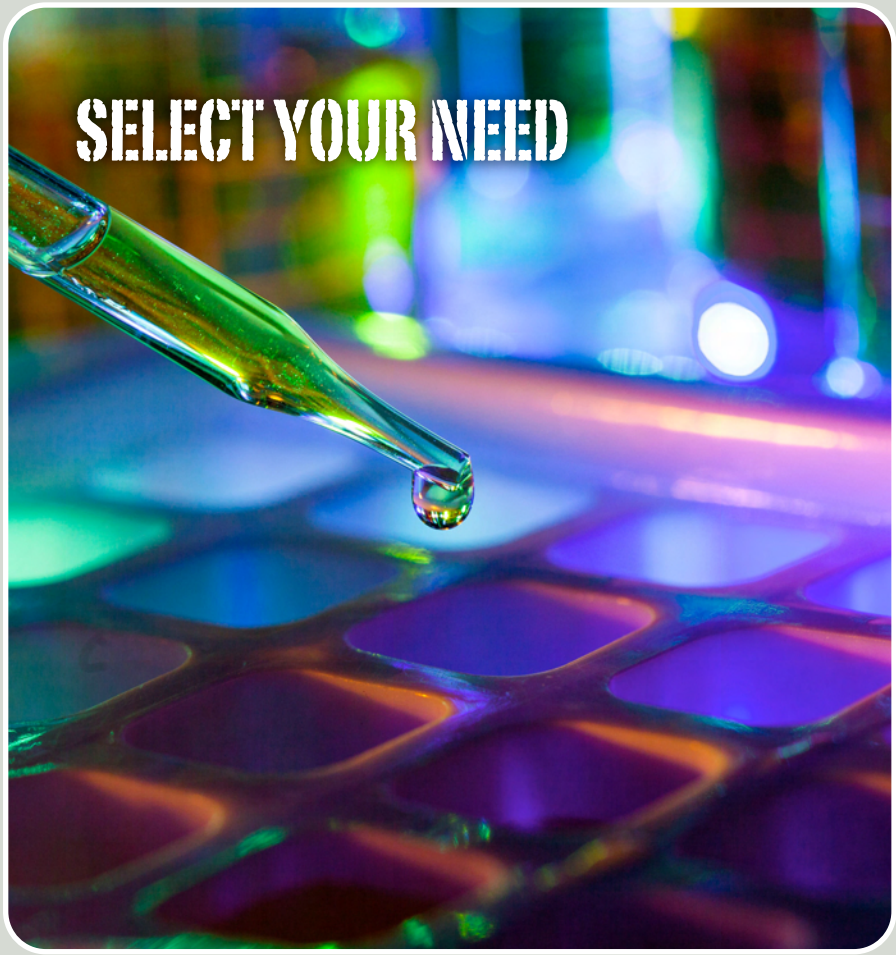
THE PLATFORM

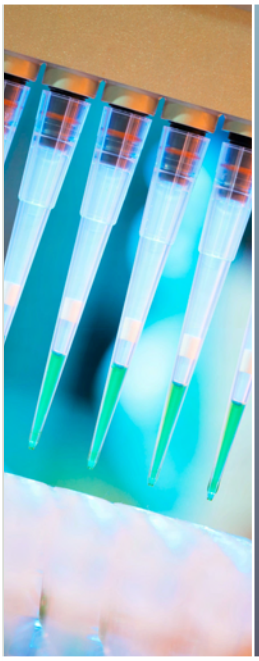


iVV assay

Disease focus

There are five different iVV assay reagent kits available. Each patient can be tested on all the plates. The disease areas stated are only recommendations.

"iVV assay™" the combined platform with instrumentation, reagents and quality management

PRODUCT CODE: PRODUCT NAME:	QS-IVV-H-20 IVV ASSAY REAGENT KIT (HEMATOLOGY)	QS-IVV-S-20 IVV ASSAY REAGENT KIT (BODY CAVITY)	QS-IVV-L-20 IVV ASSAY REAGENT KIT (MIXED PURPOSE)	QS-IVV-E-20 IVV ASSAY REAGENT KIT (EXPERIMENTAL)	QS-IVV-X-20 IVV ASSAY REAGENT KIT (CUSTOM)
	**Substances located on the 384-well plate** 4-OH cyclophosphamide 6-mercaptopurine Arsenic trioxide Bendamustin Bortezomib Busulfan Carfilzomib Carmustine Chlorambucil Cisplatin Clofarabine Cytarabine Dasatinib Daunorubicin Dexamethasone Doxorubicin Etoposid Fludarabin Idarubicin Ifosfamide Imatinib Lenalidomide Melphalan Methotrexate Methylprednisolone Mitoxantrone Nelarabine Thalidomide Vincristine Vinorelbine	**Substances located on the 384-well plate** 5-Fluorouracil Afatinib Axitinib Carbazitaxel Capecitabine Carboplatin Dabrafenib Dactinomycin Demecolcine Docetaxel Epirubicine Eribulin Erlotinib Estrmustine Everolimus Gefitinib Gemcitabine Irinotecan Lapatinib Mitomycin Oxaliplatin Paclitaxel Pazopanib Pemetrexed Regorafenib Sorafenib Sunitinib Temozolomide Temsirolimus Topotecan	**Substances located on the 384-well plate** 6-thioguanine Amsakrin Anagrelid ATRA Bexarotane Bleomycin Bosutinib Cladribine Crizotinib Dacarbazid Decitabine Hydroxyurea Ibrutinib Lomustine Mitotane Nilotinib Pixantrone Pomalidomide Ponatinib Rapamycine Ruxolitinib Teniposide Thiotepa Trabectedine Vandetanib Vidaza (Azacitiden) Vinblastin Vindesine Vinflunine Vismodegib	**Substances located on the 384-well plate** Auranofin Captopril Cimetidine Dichloroacetate Disulfiram Enzastaurin Etoglucid Fotemustine Furamidine Idelalisib IPI-145 Ixabepilone Mebendazole Metformin Methadone Miltefosine Mocetinostat Olaparib Pentamidine Pralatrexate Procarbazine Raltitrexed Ribavirin Romidepsin Teniposide Trametinib Vatalanib Vorinostat YM-155 Zoledronate	**Substances located on the 384-well plate** Free choice of 30 different drugs from the plates: QS-IVV-H-20 QS-IVV-S-20 QS-IVV-L-20 QS-IVV-E-20

QS-HSC-HAEMA QantaScope HexascopeHAEMA™ automated scanner and image analyzer (CE IVD)

QS-QC-CL QantaScope iVV assay™ QC cell line
QS-QC-BEADS-04 QantaScope Quality Control Bead kit - QantaBead

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