

HEXASCOPE HAEMA™

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DRUG SENSITIVITY ASSAY

Assisting Personalized Oncotherapy

QantaScope HexascopeHAEMA™ automated scanner and image analyzer is specially designed for use in personalized cancer therapy. There are several reasons why individualized cancer care might be required. One reason is when the diagnosis does not have any specific treatment option or the disease is very complex and most of the protocols fail. Patients, exhausting potential treatments would need to further investigate alternative chemotherapy options.

HexascopeHAEMA™ automated scanner and image analyzer is a brand new diagnostic platform to find the best medicine by monitoring the primary tumor cells in the patient's fresh sample (blood, bone-marrow or body cavity fluid). The system can be used together with iVV assay reagent kits but also as a stand alone device for patient preselection in clinical trials or for drug development projects at a very early stage in compound screening. The scanner can visualize every single tumor

cell and monitor their survival in the presence of different substances. The analysis software creates a result report for the clinician and ranks the drugs according to their tumor cell killing efficacy. This is a unique tool in the daily routine diagnostics or different phases during drug development.

The diagnostic platform uses a unique and patented cell culture media which keeps the tumor cell close to their original properties.



ROUTINE CANCER DIAGNOSTICS



CLINICAL TRIALS



PATIENT PRESELECTION

HEMATOLOGICAL MALIGNANCIES



LEUKEMIA

Chemo-
therapy

HEALTH



TREATING HEMATOLOGICAL MALIGNANCIES CAN BE CHALLENGING (FOR INSTANCE, AML, PROGRESSIVE CLL, GLIVEC RESISTANT CML).

HEXASCOPEHAEMA™ AUTOMATED SCANNER USED WITH IVV ASSAY REAGENT KITS CAN HELP MAKE THE RIGHT DECISION OR IN PATIENT FOLLOW-UP.

BODYCAVITY FLUIDS



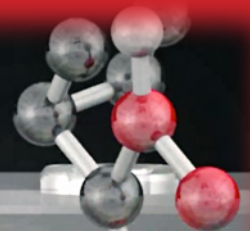
SOME ADVANCED SOLID TUMORS CAN PRODUCE BODY CAVITY FLUIDS, LIKE ASCITES OR PLEURAL EFFUSIONS WITH HIGH NUMBER OF TUMOR CELLS, THEREFORE, THEY ARE PERFECT CANDIDATES FOR IVV ASSAY AND HEXASCOPEHAEMA™ TESTS. PATIENTS WITH AGGRESSIVE TUMORS, WHO HAVE ALREADY EXHAUSTED THE FIRST AND SECOND LINE TREATMENT PROTOCOLS CAN MANY TIMES BE SENSITIVE FOR SOME NEW THERAPIES.

THE PLATFORM

VISIT
www.qantascope.com



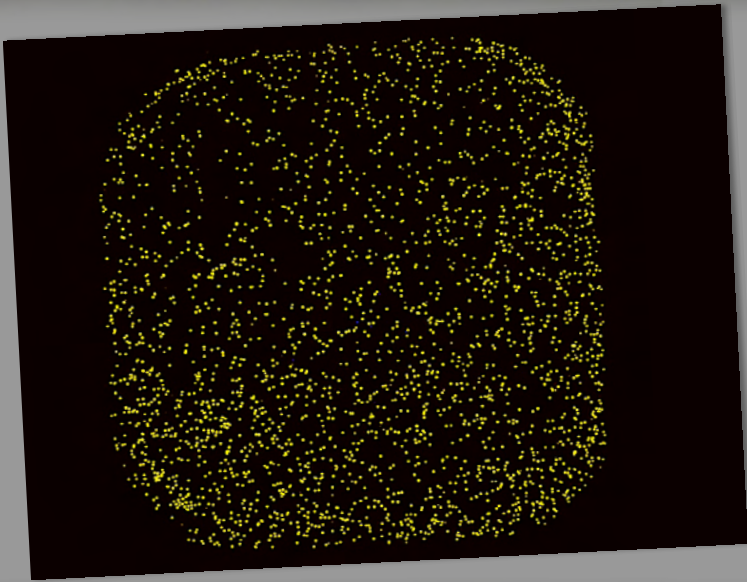
BARCODE SYSTEM



DIFFERENT CONCENTRATIONS

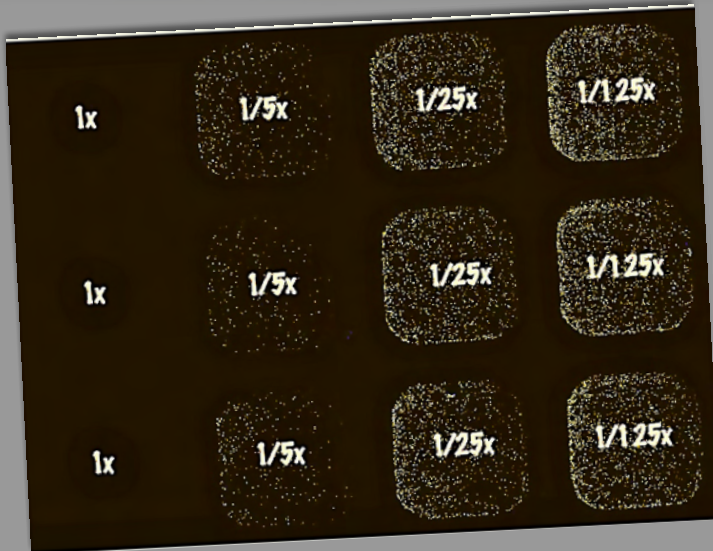


HEXASCOPEHAEMA™ AUTOMATED SCANNER AND IMAGE ANALYZER DETECTS FLUORESCENT LABELLED OBJECTS ON A 384-WELL PLATE. IT IS USED AS AN IN VITRO DIAGNOSTIC DEVICE, GENERATING ADDITIONAL DIAGNOSTIC INFORMATION ABOUT THE PATIENT'S DRUG SENSITIVITY PROFILE ASSISTING INDIVIDUALIZED CANCER THERAPY. THE SYSTEM GENERATES THE CAPTURING AND DATA ANALYSIS ALMOST AT THE SAME TIME. RESULT FILES CAN BE PRINTED OR DIGITALLY TRANSFERRED TO THE CLINICIAN.



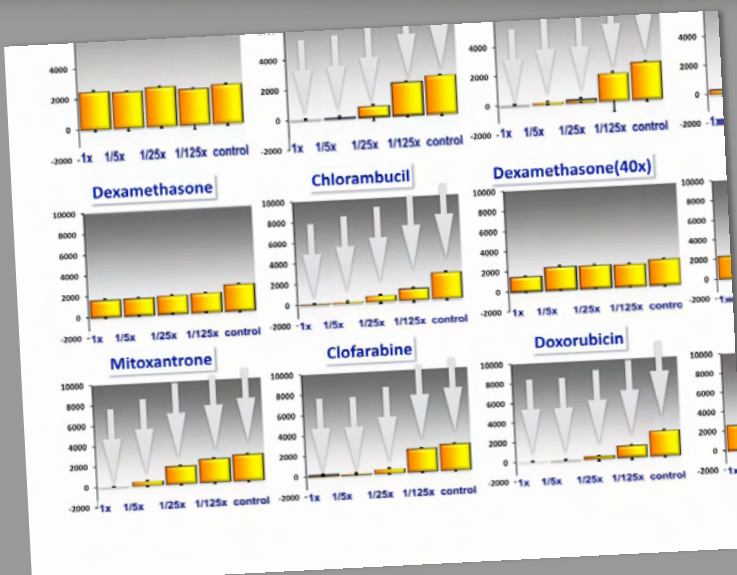
SINGLE CELL MEASUREMENTS

DIFFERENT FLUORESCENT DYES LABEL THE LIVE AND DEAD CELLS. THE SYSTEM COUNTS EVERY SINGLE CELL ACCORDING TO FIVE DIFFERENT STATISTICAL ALGORITHMS WHICH MAKE THE ANALYSIS VERY ROBUST. EVEN SMALLER CELL CLUMPS CAN BE MONITORED THIS WAY.



CONCENTRATION DEPENDENT DRUG EFFECT

THE PATIENT'S TUMOR CELLS ARE EXPOSED TO FOUR DIFFERENT CONCENTRATIONS OF THE SAME SUBSTANCE WHERE EVERY SUBSTANCE IS REPRESENTED AS A TRIPLICATE FOR QUALITY ASSURANCE AND TO MINIMIZE ERRORS.



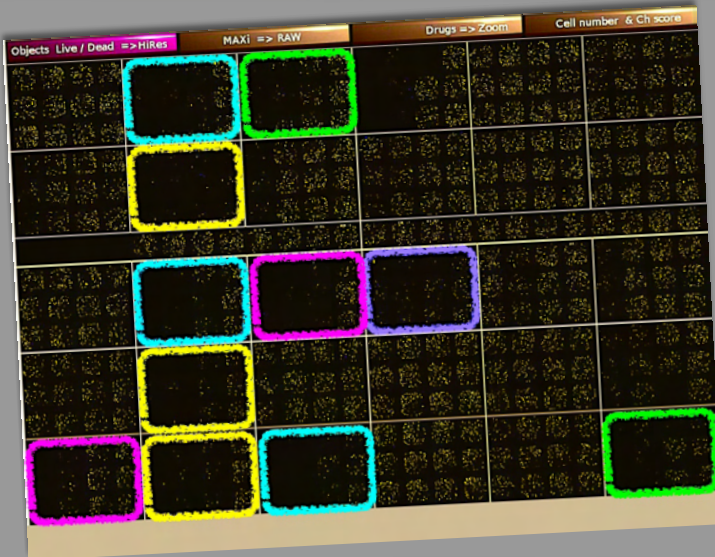
TITRATION CURVES

AN ADDITIONAL FEATURE OF THE SOFTWARE IS THE TITRATION CURVES, WHERE CELL SURVIVAL CAN BE MONITORED AND QUALITY MANAGEMENT IS ENSURED. DRUG EFFECT CAN EASILY BE EXAMINED AND WORK PERFORMANCE CAN BE VERIFIED.



AUTOMATIC QUALITY CONTROL

HEXASCOPEHAEMA™ AUTOMATICALLY GENERATES A RESULT REPORT FILE WITH AN INBUILT QUALITY CONTROL. DIFFERENT FACTORS MEASURE THE DIFFERENT STAGES OF THE WORKFLOW. IF A FACTOR WOULD MAKE THE RESULT INVALID, A WARNING MESSAGE IS SENT TO THE USER.



BARCODE DRIVEN DRUG LOCALIZATION

EACH DRUG COATED 384-WELL PLATE HAS A BARCODE WHICH INCLUDES ALL THE NECESSARY INFORMATION CONCERNING THE DIFFERENT SUBSTANCE LOCALIZATIONS. DIFFERENT KINDS OF SUBSTANCE PLATES CAN BE ORDERED, BOTH AS PREPRINTED OR AS CUSTOM DESIGNED.



HIGH SENSITIVITY AND SPECIFICITY

A MINIMAL AMOUNT OF TUMOR CELLS AND PATIENT SAMPLES MAKE IT POSSIBLE TO SCREEN A LARGE NUMBER OF SUBSTANCES. DEPENDING ON THE TUMOR CELL CONTENT OF THE SAMPLE, 0,2 ML-1 ML IS USUALLY ENOUGH TO SCREEN BETWEEN 30-90 DIFFERENT DRUGS AND EXAMINE THEIR EFFECT ON THE PATIENT'S TUMOR CELLS.

Defining the unique drug sensitivity profile of the patient

The automatically generated report files define whether the patient has a high-, moderate- or low sensitivity for the drugs being examined. High sensitivity means that the freshly isolated tumor cells from the patient sample were killed already by the highest possible dilution of that substance according to a concentration dependent pattern. The highest dilution is 125x lower than the dosage recommended for in vivo therapy use. That substance which has a KE% value closest to 100, demonstrates the best drug for therapy use. The chart can be easily evaluated by the user, since the drugs are ranked. The best fitting

medicines for that specific patient are represented at the top of the chart.

HexascopeHAEMA™ automated scanner and image analyzer includes the scanning unit, the computer with a flat screen monitor and a barcode reader. Quality control is recommended to be run by the user quarterly with QantaScope Quality Control Bead kit-QantaBead. To improve technical skills and for assay quality management, the use of QantaScope iVV assay QC cell line is highly recommended.

IVV ASSAY THERAPY RECOMMENDATION IS A DIAGNOSTIC RESULT AND THE DECISION ABOUT THE FINAL TREATMENT MUST BE MADE BY THE ONCOLOGIST OR HEMATOLOGIST, WHEN GENERAL HEALTH STATUS OF THE PATIENT, OR OTHER DIAGNOSTIC PARAMETERS MUST BE TAKEN INTO CONSIDERATION!

REPORT FILE

HEMOTHERAPY

CLINICAL REPORT FILE

CELL KILLING EFFICIENCY

(in order of effect)

| | not effective | moderately effective | highly effective |
|-----------------------|---------------|----------------------|------------------|
| Colchicine | | | |
| Doxorubicin | | | |
| Daunorubicin | | | |
| Chlorambucil | | | |
| Idarubicin | | | |
| Vinorelbine | | | |
| Clofarabine | | | |
| Bortezomib | | | |
| Fludarabine | | | |
| Cladribine | | | |
| Mitoxantrone | | | |
| Epirubicin | | | |
| Vincristine | | | |
| Cytarabine | | | |
| Amsakrin | | | |
| Vinblastin | | | |
| Dexamethasone | | | |
| Prednisolone | | | |
| Etoposid | | | |
| 4-OH cyclophosphamide | | | |
| Dexamethasone(40x) | | | |
| Rapamycin (Sirolimus) | | | |
| 6-mercaptopurine | | | |
| Cisplatin | | | |
| Arsenic trioxide | | | |
| Hydroxyurea | | | |
| Gemcitabine | | | |
| Methotrexate | | | |
| Bendamustin | | | |
| 6-thioguanine | | | |

KILLING EFFICIENCY VALUE

THERAPY RECOMMENDATION

iVV assay results

- Clinical report
- Killing efficiency
- Drug response titrations
- Drug list
- Plate images
- General information



ORDERING INFORMATION

INSTRUMENTATION AND QUALITY MANAGEMENT

| product code | product name |
|----------------|------------------------------------------------------------------------------|
| QS-HSC-HAEMA | QantaScope HexascopeHAEMA™™ automated scanning and analyzing system (CE IVD) |
| QS-QC-BEADS-04 | QantaScope Quality Control Bead kit - QantaBead |

REAGENTS AND QUALITY MANAGEMENT

| product code | product name |
|--------------|---------------------------------------------------------------------------------|
| QS-IVV-H-20 | QantaScope iVV assay reagent kit - hematology (CE IVD) |
| QS-IVV-S-20 | QantaScope iVV assay reagent kit - ascitic fluid and pleural effusions (CE IVD) |
| QS-IVV-L-20 | QantaScope iVV assay reagent kit - mixed purpose (CE IVD) |
| QS-IVV-E-20 | QantaScope iVV assay reagent kit - experimental (CE IVD) |
| QS-IVV-X-20 | QantaScope iVV assay reagent kit - custom made selection (CE IVD) |
| QS-QC-CL | QantaScope iVV assay QC cell line |