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Biochip
Check it out!

Greiner Bio-One – Competences in biochips



The complete deciphering of the human genome and the ongoing sequencing of animal, plant and microbial genomes has opened up new analytical possibilities and techniques. Complex analyses, e.g. of mutations and functions or for genotyping, can be performed today within a few hours with the help of microarrays or "biochips". Greiner Bio-One develops and manufactures high-quality biochips for human diagnostics, consumer protection and for

quality assurance within the pharmaceutical industry. Our expertise comprises the development and production of our own innovative biochip platforms for the parallel analysis of samples, the selection of probes, and the validation and production of biochips according to the European Guideline 98/79/EG. Benefit from our knowledge and take advantage of our competent consulting, to develop "your" biochip in a reliable and fast manner.

Service offerings – Comprehensive and competent



Development and production

of “ready-to-use” microarrays for human diagnostics, food surveillance and biopharmaceutical production control



Manufacture of innovative platforms

from plastic in slide and micro-plate format (HTA™, High-Throughput microArraying) for the parallel analysis of microarrays



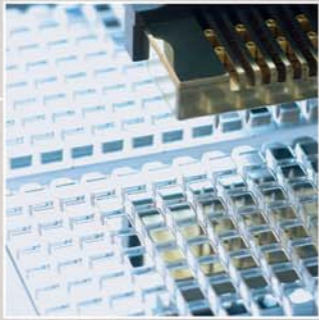
Preparation of qualitatively high-grade 3-D surfaces

for binding DNA or proteins in combination with optimised buffer sets



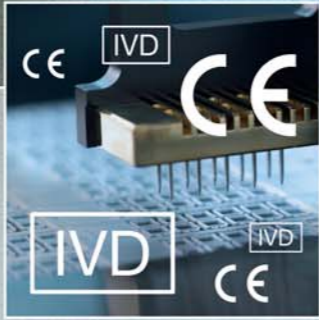
Automatic detection and analysis

of Greiner Bio-One “oCheck” biochips with an EU-conforming hardware (Check Scanner™) and software (CheckReport™) package



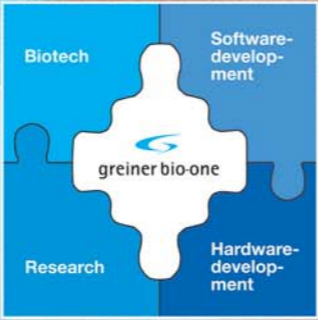
Advising, developing and producing

“custom made arrays” for high-throughput on HTA™Platforms



CE-conforming production and documentation

of microarrays for use as IVD



Effectiveness enhancement through cooperation

with national and international partners



Professional market research



Global marketing



Our own proprietary rights and patents

Biochip products – Tailor-made solutions

ParoCheck®, CarnoCheck®, PapilloCheck® – Ready-to-use kits

All of the Greiner Bio-One “ready-to-use” oCheck biochips consist of complete test systems, with all the necessary buffers and solutions. Extensive “on chip” controls guarantee error-free results.

ParoCheck®: Inflammation of the gums and the paradontium are among the most frequent human diseases. Certain bacterial species can serve as indicators to detect such changes early and thereby to be able to treat successfully. ParoCheck® is the first biochip approved as an “In-Vitro-Diagnostic” (IVD), and with it up to 20 different characteristic indicative pathogens can be detected.

CarnoCheck®: Consumer protection and quality assurance play an increasing role in public awareness, especially in the production of foods. Greiner Bio-One has taken into account this need for transparency with the development of CarnoCheck®. With this biochip 8 different animal species can be unequivocally identified in foods or other products.

PapilloCheck®: Another of Greiner Bio-One’s biochips serves for the early recognition of human papillomaviruses (HPVs). High risk types of human papillomaviruses are causative agents in the occurrence of cervical cancer. With the newly developed biochip PapilloCheck® a total of 18 of the “high risk” HPV types and 6 “low risk” HPV types can be identified.

HTA™Platforms

In academic research with “high density microarrays” some samples are investigated for thousands of parameters whilst compared to diagnostics thousands of samples are analysed for a few expressive markers. Therefore parallel comparison and automation play a decisive role. In order to take this into account, Greiner Bio-One has developed new HTS platforms made from plastic especially for use in biochip technology – the HTA™Platforms (High-Throughput microArraying).

HTA™Slide12: The plastic HTA™Slide12 has the dimensions of a standard 25 x 75 mm glass slide but is partitioned into 12 flat compartments, each with a printable surface of 6 x 6 mm. Therefore 12 samples can be processed simultaneously.

Slide x 96 = 1x HTA™Plate: A much higher sample throughput at lower cost is made possible by the HTA™Plate. It offers for the first time the possibility of producing and processing up to 96 microarrays in the format of an SBS-conforming microplate platform.

3-D Surfaces and Buffers

For the successful use of microarrays in routine laboratory work, besides the use of high-quality microarray platforms, the quality of the surface functionalizations and a suitably chosen buffer system are of crucial importance. In close collaboration with PolyAn and Scienion, Greiner Bio-One has developed a broad spectrum of different surfaces and buffer systems for HTA™Platforms.



CheckScanner™ and CheckReport™ Software

Biochips for human diagnostics, as In-Vitro-Diagnostics, are subject to the conformity procedure under the German Medical Product Law (MPG) and the European Guideline 98/79/EC. Among other requirements, this calls for the provision and use of appropriate hardware and software. With the laser supported CheckScanner™ developed by DITABIS and the CheckReport™ Software developed by MicroDiscovery, Greiner Bio-One has achieved this requirement. The coordinated parallel development of compatible scanner and software permits the fully automatic detection and analysis of up to 4 HTA™Slides or one HTA™Plate. Through the use of innovative control systems on the individual “oChecks”, which are monitored by the CheckReport™ Software during the evaluation, false negative or false positive results are virtually excluded. The CheckReport™ Software is composed of three subsystems:

- **CheckReport™SampleSheet:** This unequivocally links patient data with an individual barcode on an “oCheck” biochip.
- **CheckReport™Result:** The module is based on the successful GeneSpotter-software of MicroDiscovery and contains the actual evaluation.
- **CheckReport™Admin:** This module controls the user management and prevents the misuse or manipulation of data.

Quality standard according to DIN EN ISO 9001 and DIN EN ISO 13485

Greiner Bio-One was already validated and certified in 1994 according to DIN EN ISO 9001. Our high standard for the production processes, quality control and our organisation were confirmed by further recertifications in 1997, 2000 and 2003 according to the new DIN EN ISO 9001:2000 standard. In order to meet the high international standards required as a manufacturer of medical products, since 2004 we are additionally certified according to DIN EN ISO 13485:2003 for medical products. Through the application of the newest finishing technologies, the manufacture under special environmental conditions, as well as the employment of qualified staff, the quality of our products and processes is being continually improved.

CE-labelling and EU-conformity

Through the European Guideline 93/42/EWG for medical products and 98/79/EC for In-Vitro-Diagnostics and the associated legal stipulations, some of our products are classified as medical products or In-Vitro-Diagnostics. These products are recognizable by the CE-label, which is prominently visible on the packaging. Through this labelling we conform with the requirements of these EU-Guidelines for medical products and In-Vitro-Diagnostics.

