Suicidality test being brought to market

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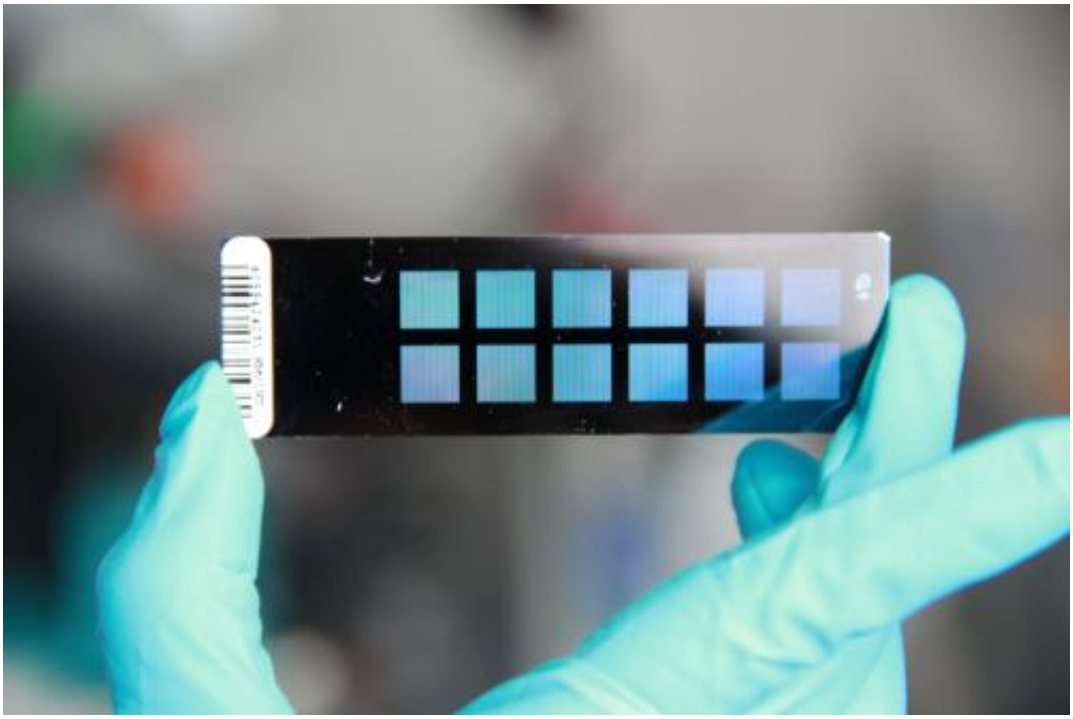

DNA microarrays are used for diagnostics and to study the expression of genes. A further application is that of genome analysis. Credit: MPI of Psychiatry

The new test, based on research carried out at the Max Planck Institute of Psychiatry, should help doctors to decrease the risk of suicidality in patients treated with antidepressants who show certain gene markers. Sundance is completing a new round of funding to extend the initial validation results reported by the Institute. The company plans to launch the test immediately as a laboratory developed test. In addition, clinical studies in support of a U.S. Food and Drug Administration submission

for market clearance, CE marking and reimbursement will be initiated. Sundance expects to submit its application to the agencies within 18 months.

Researchers at the Max Planck Institute of Psychiatry discovered when suicidality occurred it happened within two weeks of beginning treatment, or increasing dosage, for 59% of patients. Altogether, 8.1% of patients studied suffered from this adverse side effect of antidepressant medications. Since 2005, in the United States, Canada and some European countries, antidepressants have carried a warning alerting the doctor and the patient to the serious risk of medication-induced suicidality. Up until now, however, doctors have had no indications as to which patients may be at risk. Sundance CEO Kim Bechthold stated, "Our hope is that the new test will assist the physician in significantly reducing the risk of suicide emerging from antidepressant drug use and will provide patients and families with valuable personal information to use with their doctors in weighing the risks and benefits of the medications."

Scientists at the Max Planck Institute of Psychiatry in Munich have now discovered 79 genetic biomarkers that had a 91% probability of correctly classifying patients at risk of antidepressant-induced suicide.

The researchers also discovered that the increased risk for suicide is not limited to individuals under the age of 25, as described in the warning by the American regulatory agency FDA. Instead, the risk was found in the studies to be present across all ages from 18 to 75. In the United States, more than 9 million new antidepressant drugs are prescribed annually (IMS 2006 National Prescription Drug Audit).

The licensing agreement with Sundance Diagnostics was concluded with Max-Planck-Innovation, the Max Planck Society's technology transfer organization.

More information: Andreas Menke, Katharina Domschke, Darina Czamara, Torsten Klengel, Johannes Hennings, Susanne Lucae, Bernhard T Baune, Volker Arolt, Bertram Müller-Myhsok, Florian Holsboer & Elisabeth B Binder, Genome-Wide Association Study of Antidepressant Treatment-Emergent Suidical Ideation, *Neuropsychopharmacology*. February 2012; 37(3): 797. Online Publication 26 October 2011. DOI: 10.1038/npp.2011