SensiScreen® assays are real-time PCR-based reactions for somatic mutation detection in cancer patients. SensiScreen® combines high sensitivity with multiplexing capabilities, ease-of-use and is designed to work on standard real-time PCR equipment. Sensitive detection of somatic mutations by SensiScreen® is achieved with PentaBase's novel and selective INA® technologies including the use of BaseBlockers™ that suppress false positive signals from wild type templates.

Key features
- High sensitivity - down to one copy detection
- Simplex and multiplex configurations
- Mutation detection in solid and liquid biopsies
- Open platform designs

From sample to answer in less than three hours
SensiScreen® assays are supplied as either "Ready to use" or as "Dispense Ready" mixes. Ready to use assays are pre-dispensed in PCR strips and require only addition of genomic DNA (gDNA) for somatic mutation testing. Dispense-ready mixes include oligonucleotides and master mix in separate tubes ready to be dispensed and added gDNA. The technology is applicable on standard real-time equipment using standard procedures and results can be ready in less than three hours from receiving a sample (including automated DNA extraction).

Streamline your workflow with SensiScreen® multiplex assays

More information at www.pentabase.com
Technology

Ultra-sensitive detection of somatic mutations by SensiScreen® is possible with PentaBase's novel and selective technologies, comprising:

1. **HydrolEasy™** dual-labelled probes with significantly improved signal-to-noise ratio and higher specificity compared to conventional hydrolysis probes.
2. **Suprimer™** DNA primers modified with pentabases for specific and sensitive amplification.
3. **BaseBlockers™** suppressing false positive and negative signals from wild type templates and ensuring high specificity and robustness of the assays.

SensiScreen® assay design

---

**Features**

- **Solid and liquid sample analysis**: Supplied in both a FFPE version for analysis of solid biopsies and a Liquid version for analysis of liquid biopsies containing small amounts of DNA.
- **High Sensitivity**: SensiScreen® FFPE assays have a limit of detection between 0.1% and 1% mutant DNA in a wild type background. SensiScreen® Liquid products detect down to one copy of mutant DNA.
- **Easy and fast**: Easy to set up (hands-on-time <2 min/sample) and takes less than three hours from sample to result including DNA extraction.
- **State of the art**: Based on PentaBase's proprietary INA® technologies. Finds more true mutation positive samples compared to other common methods for detecting somatic mutations (Riva et al. 2017).
- **Proven**: SensiScreen® CE IVD assays are clinically validated in Switzerland and Denmark and are certified in accordance to the EU guidelines 98/79/EC Medical equipment for in vitro diagnostics.
- **Simplex and multiplex**: Supplied in multiplex configurations for mutation screening and simplex configurations for genotyping and monitoring.
- **Open qPCR platform designs**: Designed to work on standard real-time PCR instruments and validated on commonly used platforms*.

---

*Rotor-Gene (Qiagen), MX3000P/3005P (Agilent), LightCycler® 96 + 480 (Roche), CFX96™ (Bio-Rad), ABI 7500/7900HT (Applied Biosystems), MIC (Bio Molecular Systems) and MyGo Pro (IT-ISS Life Science)
Early detection and monitoring with ultra high sensitivity

SensiScreen® Liquid assays are designed for early detection and monitoring of somatic mutations in liquid biopsies using standard equipment. With SensiScreen® Liquid, it is possible to monitor changing levels of mutant DNA and newly developed mutations in circulating cell-free DNA (ccfDNA) shed into the blood or other liquid samples. In this way, SensiScreen® Liquid can support the selection of the most appropriate personalized treatment in a timely manner. SensiScreen® Liquid assays are able to detect down to a single copy of mutated DNA in a background of wild type DNA.

- Analysis of liquid biopsies
- Early detection and monitoring of cancer DNA biomarkers
- Detects down to 1 copy of mutated DNA
- From biopsy to result in < 3 hours

Detecting down to one copy

The figures below illustrate a SensiScreen® Liquid assay detecting one copy of mutant DNA. A DNA sample from a patient heterozygous for an EGFR Exon 19 Deletion were diluted to approximately 3 copies per well and an assay performed with 12 replica.
Choose SensiScreen® Liquid for fast and sensitive cancer monitoring using liquid biopsies

A colorectal cancer case study using SensiScreen® BRAF V600E Liquid for disease monitoring. Approx. 200 µl of plasma were used.
Detection in solid biopsies
SensiScreen® FFPE assays are designed for detection of somatic mutations from genomic DNA in solid biopsies like fresh, frozen, FFPE tissue, or other samples with high amounts of DNA. SensiScreen® FFPE assays are able to robustly detect 0.25-1% mutation in a 50 ng wild type background.

- **Analysis** of primary tumors and metastases
- **Multiplex** assays for screening of cancer mutation hotspots
- **Simplex** assays for genotyping and has confirmation
- SensiScreen FFPE assays are applicable to fresh, frozen or FFPE biopsies

SensiScreen® KRAS G12V sensitivity

Experimental data example
Rotor-Gene 6000 PCR amplification plots of SensiScreen® KRAS G12V simplex and multiplex assays using serial dilutions of mutated DNA in a wild type background. 50 ng (about 16,000 copies) of human genomic DNA was added to each reaction. The threshold was set at 10% of the average fluorescence signal of the reference assay at cycle 45. Legend describes the fraction of mutated G12V cell line DNA in a wild type background. 0.01% corresponds to 1-2 copies of mutant DNA. For sensitivities of other KRAS Exon 2 hotspot mutations please refer to Riva et al. 2017.

Use SensiScreen® as NGS confirmation
SensiScreen® is the optimal solution to confirm your NGS findings, by providing a directed sensitive assay with little hands-on time and a fast answer. All SensiScreen® assays are available as single nucleotide variant kits on demand.

More information at www.pentabase.com
Colorectal Cancer (CRC) is one of the leading causes of cancer related mortality. Progression of CRC is associated with accumulation of mutations in the EGFR signalling pathway(s) involving genes like KRAS, NRAS, BRAF and PIK3CA. Treatment efficacy of available therapies (like the selection of EGFR antagonizing antibodies) rely on tumor mutation profiling, stratification and monitoring.

PentaBase SensiScreen® CRC panels have been developed to support initial selection of adequate treatment regimen and subsequent monitoring of treatment efficacy and resistance development.

### SensiScreen® Liquid and FFPE colorectal cancer panels

<table>
<thead>
<tr>
<th>KRAS Exon 2+3+4 Multiplex</th>
<th>NRAS Exon 2+3+4 Multiplex and Simplex</th>
</tr>
</thead>
<tbody>
<tr>
<td>KRAS Exon 2 Multiplex and Simplex</td>
<td>NRAS Exon 2 Multiplex and Simplex</td>
</tr>
<tr>
<td>KRAS G13D</td>
<td>NRAS G13A/C/D/R/S/V</td>
</tr>
<tr>
<td>KRAS Exon 3 Multiplex and Simplex</td>
<td>NRAS Exon 3 Multiplex and Simplex</td>
</tr>
<tr>
<td>KRAS Q61H1/H2/E/K/L/R</td>
<td>NRAS Q61H1/H2/K/L/R</td>
</tr>
<tr>
<td>KRAS A59G/T</td>
<td>NRAS A59D/T</td>
</tr>
<tr>
<td>KRAS K117N1/N2</td>
<td>NRAS Exon 4 Multiplex and Simplex</td>
</tr>
<tr>
<td>KRAS A146P/T/V</td>
<td>NRAS K117N1/N2</td>
</tr>
<tr>
<td>BRAF V600D/E/K/R Multiplex and Simplex</td>
<td>PIK3CA H1047L/R/Y Multiplex and Simplex</td>
</tr>
</tbody>
</table>

SensiScreen® assays are supplied as either “Ready to use” or “Dispense Ready” mixes. Ready to use assays are pre-dispensed in PCR strips and require only addition of gDNA for somatic mutation testing. Dispense ready mixes include oligonucleotides and master mix in separate tubes ready to be dispensed and added gDNA. The technology is applicable on standard real-time equipment using standard procedures and results can be ready in less than three hours from receiving a sample (including automated DNA extraction).

More information at www.pentabase.com
Colorectal Cancer Panels
PentaBase offers SensiScreen® somatic mutation panels for tumor development monitoring and stratification of colorectal cancer patients with unprecedented sensitivities.

**SensiScreen® Liquid monitoring**
Key features
- Detects down to 1 copy of mutated DNA
- Analysis of liquid biopsies
- Early detection and monitoring of cancer DNA
- From biopsy to result in < 3 hours

**SensiScreen® FFPE tumor stratification**
Key features
- Analysis of primary tumors and metastases
- Multiplex assays for hotspot CRC mutations
- Simplex assays for genotyping and NGS confirmation
- SensiScreen® FFPE assays are applicable to fresh, frozen and FFPE biopsies

**Colorectal Cancer Disease Progression Monitoring**

SensiScreen® Liquid BRAF V600E

[Graph showing changes in BRAF V600E copies in plasma during chemotherapy and targeted therapy]

More information at www.pentabase.com
Non-small-cell lung cancer (NSCLC) is the most widespread type of lung cancer and accounts for the highest mortality rates among cancers. NSCLC is relatively insensitive to chemotherapeutics and radiation therapy, but recently a number of new drugs have been developed. PentaBase's SensiScreen® Lung cancer panels have been developed to support initial selection of adequate treatment regimen and subsequent monitoring of treatment efficacy and resistance development.

SensiScreen® Liquid and FFPE lung cancer panels

- EGFR Exon 18+19+20+21 Multiplex
- EGFR G719A/C/S
- EGFR Exon 19 Deletions (35 deletions)
- EGFR S768I
- EGFR T790M
- EGFR Exon 20 Insertions (22 insertions)
- EGFR L858R
- EGFR L861Q
- EGFR Exon 19 Deletions+T790M+L858R
- KRAS Exon 2+3+4 Multiplex
- KRAS Exon 2 Multiplex and Simplex
- KRAS G12A/C/D/R/S/V
- KRAS G13D
- KRAS Exon 3 Multiplex and Simplex
- KRAS Q61H1/H2/E/K/L/R
- KRAS A59G/T
- BRAF V600D/E/K/R Multiplex and Simplex
- BRAF V600E Simplex
- NRAS Exon 2+3+4 Multiplex and Simplex
- NRAS Exon 2 Multiplex and Simplex
- NRAS G12A/C/D/R/S/V
- NRAS G13A/C/D/R/S/V
- NRAS Exon 3 Multiplex and Simplex
- NRAS Q61H1/H2/K/L/R
- NRAS A59D/T
- PIK3CA H1047L/R/Y Multiplex and Simplex

SensiScreen® assays are supplied as either "Ready to use" or "Dispense Ready" mixes. Ready to use assays are pre-dispensed in PCR strips and require only addition of gDNA for somatic mutation testing. Dispense ready mixes include oligonucleotides and master mix in separate tubes ready to be dispensed and added gDNA. The technology is applicable on standard real-time equipment using standard procedures and results can be ready in less than three hours from receiving a sample (including automated DNA extraction).
Lung Cancer Panels

PentaBase offers SensiScreen® somatic mutation panels for unprecedented sensitive tumor development monitoring and stratification of lung cancer patients.

SensiScreen® Liquid

Key features

- Detects down to 1 copy of mutated DNA
- Analysis of liquid biopsies
- Early detection and monitoring of tumor DNA
- From biopsy to result in < 3 hours

SensiScreen® FFPE tumor stratification

Key features

- Analysis of primary tumors and metastases
- Multiplex assays for hotspot lung cancer mutations
- Simplex assays for genotyping and NGS confirmation
- SensiScreen® FFPE assays are applicable to fresh, frozen and FFPE biopsies

Single copy detection by EGFR T790M Liquid

Reference

1.5 copies EGFR T790M mutant DNA

Assay

1.5 copies EGFR T790M mutant DNA

1 copy

Overlay

1.5 copies EGFR T790M mutant DNA with 50 ng WT DNA

0 copies

2 copies

0 copies

2 copies

1 copy

0 copies

2 copies

1 copy

0 copies

More information at www.pentabase.com
Malignant Melanoma Panels
Worldwide, 240,000 new patients and about 55,000 deaths relate to Malignant Melanoma (MM). MM is relatively insensitive to standard therapeutics. However, new and targeted drugs have shown promising effects depending on tumor mutation profile, making precise stratification and monitoring a request. Pentabase SensiScreen® Malignant Melanoma panels have been developed to support initial selection of adequate treatment regimen and subsequent monitoring of treatment efficacy and resistance development.

SensiScreen® Liquid and FFPE Malignant Melanoma panels

- BRAF V600D/E/K/R Multiplex and Simplex
- BRAF V600E Simplex
- NRAS Exon 2+3+4 Multiplex and Simplex
- NRAS Exon 2 Multiplex and Simplex
- NRAS G12A/C/D/R/S/V
- NRAS G13A/C/D/R/S/V
- NRAS Exon 3 Multiplex and Simplex
- NRAS Q61H1/H2/K/L/R
- NRAS A59D/T
- KIT D816H/V/Y Multiplex and Simplex

To be launched in 2019
- KIT W557R1/R2
- KIT V559A/D
- KIT L576P
- KIT K642E

SensiScreen® assays are supplied as either “Ready to use” or “Dispense Ready” mixes. Ready to use assays are pre-dispensed in PCR strips and require only addition of gDNA for somatic mutation testing. Dispense ready mixes include oligonucleotides and master mix in separate tubes ready to be dispensed and added gDNA. The technology is applicable on standard real-time equipment using standard procedures and results can be ready in less than three hours from receiving a sample (including automated DNA extraction).
Malignant Melanoma Panels
PentaBase offers SensiScreen® somatic mutation panels for tumor development monitoring and stratification of melanoma patients with unprecedented sensitivities.

SensiScreen® Liquid monitoring
Key features
- Detects down to 1 copy of mutated DNA
- Analysis of liquid biopsies
- Early detection and monitoring of cancer DNA
- From biopsy to result in < 3 hours

SensiScreen® FFPE tumor stratification
Key features
- Analysis of primary tumors and metastases
- Multiplex assays for hotspot melanoma mutations
- Simplex assays for genotyping and NGS confirmation
- SensiScreen® FFPE assays are applicable to fresh, frozen and FFPE biopsies

Single copy detection by KIT D816V Liquid

More information at www.pentabase.com