Date: 14.10.2021

**Urgent Field Safety Notice**

**SensiScreen® BRAF V600 FFPE**

For Attention of\*: Distributor and customer

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| Distributor:AmpliTech8, Avenue de Flandres Dunkerque60200 COMPIEGNEFrance |

**Urgent Field Safety Notice (FSN)**

**SensiScreen® BRAF V600 FFPE**

**Risk of failure to detect one of four target mutations**

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| 1. **Information on Affected Devices\***
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| 1. | 1. Device Type(s)\*
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| The SensiScreen® BRAF V600 FFPE assay is intended for in vitro diagnosis of four specific somatic mutations V600D, V600E, V600K and V600R in simplex. This test will provide an assessment of the presence of the examined mutations of a human genomic DNA (gDNA) sample (from formalin fixed paraffin-embedded tumor biopsies). The SensiScreen® BRAF V600 FFPE assay is not intended to be sterile.  |
| 1. | 1. Commercial name(s)
 |
| SensiScreen BRAF V600 FFPE |
| 1. | 1. Unique Device Identifier(s) (UDI-DI)
 |
| N/A |
| 1. | 1. Primary clinical purpose of device(s)\*
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| The SensiScreen® assay is intended for in vitro diagnosis of specific somatic mutations. The SensiScreen® assay is to be used by trained laboratory personnel in a professional laboratory environment with human gDNA samples (e.g. gDNA extracted from formalin fixed paraffin-embedded tissues from cancer). The SensiScreen® assay is not intended for diagnosing of cancer but only as an aid to assist the oncologist’s treatment planning. |
| 1. | 1. Device Model/Catalogue/part number(s)\*
 |
| Ref. 1402 (Dispense Ready; 20 reactions)Ref. 1403 (Dispense Ready; 50 reactions)Ref. 1836 (Ready-to-Use; 12 reactions)Ref. 1837; (ready-to-Use; 60 reactions) |
| 1. | 1. Software version
 |
| Not relevant |
| 1. | 1. Affected serial or lot number range
 |
| BV6K.15F |
| 1. | 1. Associated devices
 |
| N/A |

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| 1. **Reason for Field Safety Corrective Action (FSCA)\***
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| 2. | 1. Description of the product problem\*
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|  | SensiScreen® BRAF V600 FFPE assay was found to fail detection of one of four target mutations, the V600K mutation. |
| 2. | 1. Hazard giving rise to the FSCA\*
 |
|  | Incorrect diagnosis of the BRAF V600K mutation can be given to the patient.  |
| 2. | 1. Probability of problem arising
 |
|  | There is a probability of misinterpretation of the SensiScreen® BRAF V600 assay by the customer leading to incorrect diagnosis of the V600K mutation.There is a probability of mistake in the QC process by the manufacturer leading to release of failed batch for shipment.  |
| 2. | 1. Predicted risk to patient/users
 |
|  | From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect). |
| 2. | 1. Further information to help characterise the problem
 |
|  | N/A |
| 2. | 1. Background on Issue
 |
|  | PentaBase was made aware of the defected batch when the distributor contacted PentaBase with a customer complaint. A patient was tested through the SensiScreen® BRAF V600 FFPE assay. No mutation was found (CET REF and internal control ok), but the same patient was run in NGS and came out mutated in V600K with a correct VAF. As PentaBase reviewed the QC run file and documentation, it was found that the defected BV6K.15F batch had failed to detect the V600K mutation. The responsible QC employee failed to realize that BV6K.15F did not pass quality control and due to a Certificate of Analysis, that listed batch BV6K.14F (a previously approved batch) as the V600K specific component, batch BV6K.15F was mislabeled BV6K.14F and approved for shipment. The rejection of BV6K.15F should have called it into question but did not due to the batch being mislabeled as BV6K.14F in QC files and Certificates of Analysis. |
| 2. | 1. Other information relevant to FSCA
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|  | N/A |

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|  | 1. **Type of Action to mitigate the risk\***
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| **3.** | 1. **Action To Be Taken by the User\***

[ ]  Identify Device [x] Quarantine Device [x]  Return Device [ ]  Destroy Device[ ] On-site device modification/inspection[ ]  Follow patient management recommendations[ ]  Take note of amendment/reinforcement of Instructions For Use (IFU) [ ]  Other [ ]  None  |
| 3. | 1. By when should the action be completed?
 | Quarantine Device: 21.09.2021Follow-up patient Return Device: 22.10.2021 |
| 3. | 1. Particular considerations for: Customer

Is follow-up of patients or review of patients’ previous results recommended?All patients affected by the defected batch should be re-tested by NGS to verify results.  |
| 3. | 1. Is customer Reply Required? \*

(If yes, form attached specifying deadline for return) | Yes 22.10.2021 |
| **3.** | 1. **Action Being Taken by the Manufacturer**

[x]  Product Removal [ ]  On-site device modification/inspection [ ]  Software upgrade [ ]  IFU or labelling change  [ ]  Other [ ]  None Recalling of defected batch Verification of defected batchVerification that no other products have been affected by the defected batchDiscard defected batch |
| 3 | 1. By when should the action be completed?
 | 29.10.2021 |
| 3. | 1. Is the FSN required to be communicated to the patient /lay user?
 | No |
| 3 | 1. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?
 |
| No Not appended to this FSN |

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|  | 1. **General Information\***
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| 4. | 1. FSN Type\*
 | New |
| 4. | 1. For updated FSN, reference number and date of previous FSN
 | N/A |
| 4. | 1. For Updated FSN, key new information as follows:
 |
|  | N/A |
| 4. | 1. Further advice or information already expected in follow-up FSN? \*
 | No |
| 4 | 1. If follow-up FSN expected, what is the further advice expected to relate to:
 |
| N/A |
| 4 | 1. Anticipated timescale for follow-up FSN
 | N/A |
| 4. | 1. Manufacturer information

(For contact details of local representative refer to page 1 of this FSN*)*  |
| * 1. Company Name
 | PentaBase A/S |
| * 1. Address
 | Petersmindevej 1A, Odense C, DK-5000 |
| * 1. Website address
 | www.pentabase.com |
| 4. | 1. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. \*

Yes |
| 4. | 1. List of attachments/appendices:
 | N/A |
| 4. | 1. Name/Signature
 | Ulf Bech ChristensenCEO |
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|  | **Transmission of this Field Safety Notice** |
|  | This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)Please transfer this notice to other organisations on which this action has an impact. (As appropriate)Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.\* |

Note: Fields indicated by \* are considered necessary for all FSNs. Others are optional.