

VIGILANCE – FIELD SAFETY NOTICE			
DocNo: Onc-10172n-F3	Version: 2.2	Supersedes: v.2.1	Page 1 of 2


Field Safety Notice
URGENT

Commercial Name of Affected Product: IVDD-2 EarlyCDT-Lung test kit

Field Safety Corrective Action Identifier: FSCA-ONC-01

Type of Action: Notice

Date of issue: 9th November 2018

Attention: To the Laboratory Manager
To the attention of the Chairman Medical Board and relevant Head of Departments

Details on affected Devices:

Type of Device: EarlyCDT-Lung test kit
Model Name: IVDD-2 EarlyCDT-Lung test kit
Model Number: IVDD-2
Part Number: ECCTL2-KIT
Batch Number: M00280 kits including kit calculation software version 1.61
Reference to Manufacturer's website: <https://www.oncimmune.com/>

Description of the Problem:

Statement explaining the reasons for the Field Safety Corrective Action:
Kit calculation software version 1.61 had incorrect criteria for sample invalidation for antigens MAGE A4 and HuD. The criteria is that both concentrations of Control must fail for the sample to be invalidated, but because one of the concentrations for both of the antigens is not being used for overall test result calculation it is not possible to fulfil that criteria.

Any possible risk to patients associated with previous use of the device:
A test result may have been reported as “No significant level of autoantibodies detected”, while the sample should be reported as invalid and the test repeated.

