

FSCA/FSN REF.: DS-26-06150

**URGENT: FIELD SAFETY NOTICE (FSN)****BD Phoenix™ CPO Detect 6-well panel**

For Attention of: Clinical Personnel, Risk Managers, Laboratory Personnel, Purchasing Managers

| Action Being Taken by the Manufacturer              |                  |                          |                                        |
|-----------------------------------------------------|------------------|--------------------------|----------------------------------------|
| <input type="checkbox"/>                            | Product Removal  | <input type="checkbox"/> | On-site device modification/inspection |
| <input type="checkbox"/>                            | Software upgrade | <input type="checkbox"/> | IFU or labelling change                |
| <input checked="" type="checkbox"/>                 | Advisory         | <input type="checkbox"/> | Other                                  |
| Provide further details of the action(s) identified |                  | N/A                      |                                        |

**Information on Affected Devices**

Manufacturers SRN: US-MF-000018910

| Product name                   | Product Code (REF) | Lot number / Serial number | UDI-DI         | Expiry Date               |
|--------------------------------|--------------------|----------------------------|----------------|---------------------------|
| BD Phoenix™ Panel NMIC/ID-470  | 449724             | All lot numbers in expiry  | 30382904497249 | All lot numbers in expiry |
| BD Phoenix™ Panel UNMIC/ID-471 | 449580             | All lot numbers in expiry  | 30382904495801 | All lot numbers in expiry |
| BD Phoenix™ Panel NMIC-474     | 449727             | All lot numbers in expiry  | 30382904497270 | All lot numbers in expiry |
| BD Phoenix™ Panel NMIC-475     | 449728             | All lot numbers in expiry  | 30382904497287 | All lot numbers in expiry |
| BD Phoenix™ Panel NMIC-479     | 449515             | All lot numbers in expiry  | 30382904495153 | All lot numbers in expiry |
| BD Phoenix™ Panel NMIC-486     | 449527             | All lot numbers in expiry  | 00382904495275 | All lot numbers in expiry |
| BD Phoenix™ Panel NMIC-487     | 449528             | All lot numbers in expiry  | 30382904495283 | All lot numbers in expiry |
| BD Phoenix™ Panel NMIC-500     | 449023             | All lot numbers in expiry  | 00382904490232 | All lot numbers in expiry |
| BD Phoenix™ Panel NMIC-501     | 449041             | All lot numbers in expiry  | 00382904490416 | All lot numbers in expiry |
| BD Phoenix™ Panel NMIC-502     | 449025             | All lot numbers in expiry  | 30382904490257 | All lot numbers in expiry |
| BD Phoenix™ Panel NMIC-505     | 449056             | All lot numbers in expiry  | 30382904490561 | All lot numbers in expiry |

**Reason for Field Safety Corrective Action (FSCA)****Description of the product problem**

BD is notifying customers of a potential issue with the affected BD Phoenix™ CPO Detect 6-well panel catalogue numbers listed in the table above.

BD has received customer complaints involving quality control failures with *Klebsiella pneumoniae* ATCC BAA-1705 when using the CPO Ambler classification feature.

Based on BD's investigation, CPO Ambler classification results generated from affected Phoenix™ CPO Detect 6-well panels may lead to misclassification and should not be reported or used for clinical decision-making.

Other reportable results from the panel, such as CPO +/- results and antimicrobial AST results, may continue to be reported as described in the actions below.

Product has been distributed from 9<sup>th</sup> January 2026 and will continue to be shipped.

### **Hazard giving rise to the FSCA**

Impacted BD Phoenix™ CPO Detect 6-well panel catalogue codes may exhibit delayed growth in certain CPO Detect Ambler classification wells, which may result in a misclassification of the Ambler Class. This issue does not have any impact on valid identification of the organism, antimicrobial susceptibility results, ESBL resistance marker reporting or CPO +/- reporting. However, if an incorrect Ambler classification is used without confirmatory testing or correlation with antimicrobial susceptibility and resistance-marker data, inappropriate treatment decisions could occur. Potential health risks may include delayed optimization of antimicrobial therapy, progression of infection, and inappropriate infection control decisions. Customers should utilize confirmatory testing, consistent with their institutional laboratory procedures and applicable guidelines, to verify carbapenemase classification prior to release of Ambler classification results for clinical use.

To date, there have been 18 complaints worldwide and no adverse events worldwide related to this issue.

### **Other information relevant to FSCA**

BD will continue distribution of affected products to support continuity of testing while the root cause investigation is ongoing. BD will implement appropriate corrective actions to rectify the issue as soon as possible and will provide a follow-up communication once the issue has been corrected.

### **Device Type(s)**

The BD Phoenix™ NMIC Panel is a sealed, self-inoculating, moulded polystyrene rectangular tray with a multi-well microplate design. The tray contains dried antimicrobial agents, growth control wells, and fluorescent control wells arranged in a defined layout for Gram-negative antimicrobial susceptibility testing and carbapenemase detection. Each tray is labelled with a barcode and colour-coded identifier and is supplied within a sealed foil pouch to maintain product integrity during storage and transportation.





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**Primary clinical purpose of devices(s)**

The BD Phoenix™ NMIC Panel is intended for the invitro rapid quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of gram-negative aerobic and facultative anaerobic bacteria belonging to the order Enterobacterales and non-Enterobacterales when used with the BD Phoenix™ Automated Microbiology System.

**General Information**

FSN type: NEW

For updated FSN, reference number and date of previous FSN: N/A

For updated FSN, key new information as follows: N/A

Further advice or information already expected in follow up FSN? YES

| Type of Action to mitigate the risk                 |                                                                    |                          |                                        |                                      |                                            |                          |               |
|-----------------------------------------------------|--------------------------------------------------------------------|--------------------------|----------------------------------------|--------------------------------------|--------------------------------------------|--------------------------|---------------|
| Action To Be Taken by the User                      |                                                                    |                          |                                        |                                      |                                            |                          |               |
| <input checked="" type="checkbox"/>                 | Identify Device                                                    | <input type="checkbox"/> | Quarantine Device                      | <input type="checkbox"/>             | Cease Use                                  | <input type="checkbox"/> | Return Device |
| <input type="checkbox"/>                            | Destroy Device                                                     | <input type="checkbox"/> | On-site device modification/inspection | <input type="checkbox"/>             | Follow patient management recommendation's |                          |               |
| <input type="checkbox"/>                            | Take note of amendment/reinforcement of Instructions for Use (IFU) |                          |                                        | <input checked="" type="checkbox"/>  | Other                                      |                          |               |
| Provide further details of the action(s) identified |                                                                    |                          |                                        | Refer to considerations listed below |                                            |                          |               |

**Particular considerations for:**

1. Do not report CPO Ambler classification results generated from affected BD Phoenix™ CPO Detect 6-well panels.
2. Do not release Ambler classification information from BD Phoenix™ panels on patient reports, laboratory information system reports, electronic health records, or other clinical reporting outputs.
3. CPO positive results, other resistance marker results, and any antimicrobial AST MIC and/or SIR result from the BD Phoenix™ panels are unaffected and may still be reported according to routine laboratory reporting practice.
4. Confirmatory testing to verify appropriate Ambler Classification should be determined and performed in accordance with established laboratory procedures.

Is follow-up of patients or review of patients' previous results recommended? NO

Provide further details of patient-level follow-up if required or a justification why none is required:

There are no recommendations regarding results review or sample retesting. The detection of the CPO organisms and AST results, which primarily inform treatment selection, are not affected by the identified issue

Is customer Reply Required: YES

**FSCA/FSN REF.: DS-26-06150**

If "yes", complete the form in its entirety and return the Customer Response Form even if you no longer have any inventory remaining in your facility by **15<sup>th</sup> September 2026**.

| <b>Action To Be Taken by the Distributor</b>        |                                                                                                                 |                          |                                        |                                                                                                                  |                                                                                                                     |                          |               |
|-----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|--------------------------|----------------------------------------|------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------------|---------------|
| <input checked="" type="checkbox"/>                 | Identify Device                                                                                                 | <input type="checkbox"/> | Quarantine Device                      | <input type="checkbox"/>                                                                                         | Cease distribution                                                                                                  | <input type="checkbox"/> | Return Device |
| <input type="checkbox"/>                            | Destroy Device                                                                                                  | <input type="checkbox"/> | On-site device modification/inspection | <input type="checkbox"/>                                                                                         | Take note of amendment/reinforcement of Instructions for Use (IFU)                                                  |                          |               |
| <input checked="" type="checkbox"/>                 | Identify the facilities where you have distributed affected product and notify them immediately of this notice. |                          |                                        | <input checked="" type="checkbox"/>                                                                              | Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes |                          |               |
| <input checked="" type="checkbox"/>                 | Complete and return the Customer Response Form following completion of your reconciliation activities           |                          |                                        | <input type="checkbox"/>                                                                                         | Other                                                                                                               |                          |               |
| Provide further details of the action(s) identified |                                                                                                                 |                          |                                        | Maintain awareness of this notice and monitor to inform new customers for future shipments until further notice. |                                                                                                                     |                          |               |

|                                                                      | End User with Inventory                                                                                     | End User with ZERO inventory                                                              | Where to send completed form                                     |
|----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Purchased/distributed <b>directly</b> from BD                        | Complete the form in its entirety and ensure that all recommended actions have been implemented as required | Complete the form in its entirety and retain a copy of this notification for your records | <a href="mailto:BDFieldActions@bd.com">BDFieldActions@bd.com</a> |
| Purchased/distributed from a <b>distributor/3<sup>rd</sup> party</b> | Complete the form in its entirety and ensure that all recommended actions have been implemented as required | Complete the form in its entirety and retain a copy of this notification for your records | Return the form to your distributor                              |

**Contact details of local representative:** If you have any questions about this, please contact your local BD representative or the local BD office or e-mail [BDFieldActions@bd.com](mailto:BDFieldActions@bd.com)

### **Transmission of this Field Safety Notice**

- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred
- Transfer this notice to other organisations on which this action has an impact.
- Maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback

**The competent (Regulatory) Authority of your country has been informed about this communication to customers**