

URGENT FIELD SAFETY NOTICE

DxA 5000 Automation System

Attention Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding the Liquid Level Detection (LLD) function of the DxA 5000 Automation System.

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| ISSUE: | <p>One of the functions of DxA 5000's Liquid Level Detection (LLD) is to detect the presence of gel in between layers of fluid. When configured to allow automatic centrifugation state (spun/unspun) detection, this information is used by the DxA 5000 system to determine whether samples loaded onto the system are un-spun (whole blood with no layers; gel at the bottom) and spun (gel presence in between layers). This detection of spun vs. unspun is used by the DxA 5000 system to determine whether further centrifugation by the DxA 5000 is required.</p> <p>Beckman Coulter has received and observed some reported instances where the system was not able to distinguish between spun and unspun samples.</p> |
| IMPACT: | <p>Unspun samples may be incorrectly identified as spun by the LLD and routed for analysis without centrifugation if automatic centrifugation state (spun/unspun) detection is configured.</p> <p>Although not observed or reported, there is also a potential risk that spun samples may be incorrectly identified as unspun, and centrifuged a second time before being routed for analysis.</p> <p>In a worst case scenario where a sample is presented to a connected analyzer in a condition that does not match analytical test requirements, the analyzer could generate erroneous but believable results.</p> |
| ACTION: | <p>Option 1:</p> <ul style="list-style-type: none"> • Configure drawer settings to create spun and unspun drawers: <ul style="list-style-type: none"> • For unspun samples configure DxA 5000 settings to require centrifugation for all tubes. • For spun tubes with gel, configure DxA 5000 settings to skip centrifugation. • Visually inspect all tubes before loading them onto the DxA 5000, loading them into the appropriately configured drawers as mentioned above. <ul style="list-style-type: none"> • For unspun samples (whole blood with no layers; gel at the bottom, or no gel detected) load into the drawer configured to require centrifugation for all tubes. • For spun tubes with gel, load into the drawer configured to skip centrifugation for all tubes. <p>Option 2:</p> <ul style="list-style-type: none"> • If re-centrifugation of samples will not affect testing performed in your laboratory, you may configure the DxA 5000 settings to require centrifugation for all tubes. <p>Your Beckman Coulter Field Service Engineer will contact you to configure your settings to the Option of your choice.</p> |

FSN-18063



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| RESOLUTION: | An investigation to determine potential preventative actions is in progress and once confirmed, a software update will be released to address the issue and installed by your Beckman Coulter Field Service Engineer. |
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The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation.

If you are a centralized license holder, please provide the other affected laboratories of your organization or association with a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact Beckman Coulter via:

- Our website: <http://www.beckmancoulter.com>
- By phone: contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Franck Cheillan', with a large, stylized flourish underneath.

Franck Cheillan
Director - Quality & Regulatory Affairs

Enclosure: Response Form