



07 Sept , 2017

FIELD SAFETY CORRECTIVE ACTION NOTIFICATION
IRISpec CA/CB/CC REF 800-7702, 800-7702-FJR

Dear Iris Diagnostics Customer:
CC: Chairman Medical Board*
Head of Departments*

**applicable to affected consignees in Singapore only*

Iris Diagnostics is sending an important product notice for the IRISpec CA/CB/CC control. This letter contains important information that requires your immediate attention. Patient test results are not affected.

ISSUE:	Iris Diagnostics has become aware of an issue in which results for the IRISpec CB control for urobilinogen may fall below the lower limit of the stated quality control range.																				
IMPACT:	<ul style="list-style-type: none"> The IRISpec CB control may intermittently fail for the urobilinogen analyte when run on the iChemVELOCITY. Your laboratory will be unable to process patient samples until QC passes. This will not affect patient sample results. 																				
ACTION:	<ul style="list-style-type: none"> Implement the use of the following revised quality control ranges for IRISpec CB urobilinogen for the iChemVELOCITY. Refer to the iChemVELOCITY Operator’s Manual (P/N 300-4449FE, Appendix A; Entering Consumables Data) to change the QC range or contact your local representative for assistance. <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="3">Acceptable QC Result Ranges for iChemVELOCITY</th> </tr> </thead> <tbody> <tr> <td rowspan="6" style="text-align: center; vertical-align: middle;">IRISpec CB urobilinogen</td> <td style="text-align: center;">Change from</td> <td style="text-align: center;">4 - ≥8 mg/dl</td> </tr> <tr> <td></td> <td style="text-align: center;">70 - ≥140 μmol/L</td> </tr> <tr> <td></td> <td style="text-align: center;">(++) – (+++)</td> </tr> <tr> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">Change to</td> <td style="text-align: center;">2 - ≥ 8mg/dl</td> </tr> <tr> <td></td> <td style="text-align: center;">34 - ≥ 140 μmol/L</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;">(+) – (+++)</td> </tr> </tbody> </table> <ul style="list-style-type: none"> Please disregard any information related to control specifications that are outlined in strip package insert. Use only the specifications in this letter. 		Acceptable QC Result Ranges for iChemVELOCITY			IRISpec CB urobilinogen	Change from	4 - ≥8 mg/dl		70 - ≥140 μmol/L		(++) – (+++)			Change to	2 - ≥ 8mg/dl		34 - ≥ 140 μmol/L			(+) – (+++)
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RESOLUTION:	<ul style="list-style-type: none"> A new lower limit on the urobilinogen control range is being implemented via this letter. The new lower limit on the urobilinogen control range is being implemented to align the published IFU range with that of the allowable product claims per Beckman Coulter’s design requirements. The IRISpec CA/CB/CC package insert (and strip package insert information related to controls) will be updated to reflect changes to the lower limit of the QC range. 																				



Iris

Share this information with your laboratory staff. Retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

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

Beckman Coulter will be managing the logistics of this notice. If you have any questions or concerns regarding this notice, please contact your local support representative:

- Via our website, at <http://www.beckmancoulter.com>
- Contact your local support representative.

We apologize for the inconvenience to your laboratory.

Sincerely,



Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs
Enclosure: Response Form