XX-June-2010

Attention: Risk Management Group, Health Care Distributors

URGENT – Field Safety Notice
directCHECK® Whole Blood Control
DCJPT-A Lot Number G9DPA005
RAF 10-008

ITC has determined that the directCheck Whole Blood Control, Lot Number G9DPA005, package insert contains the incorrect acceptable performance range for J201 PT cuvettes. Our records indicate that at least one box of this product has been shipped to your facility. The correct control material range is 4.1 – 8.7 INR.

Incorrect Acceptable Performance Range	**Correct Acceptable Performance Range**
3.7 – 6.5 INR	4.1 – 8.7 INR

Use of the control with the incorrect range may falsely accept quality control tests performed on a malfunctioning test system that would otherwise be correctly rejected with use of the correct control range. ITC statistical analysis indicates that the incorrect control range allows up to 13% more false acceptance of quality control tests than does the correct control range. This is important because this PT assay monitors use of Coumadin which is a drug with a narrow therapeutic range and is highly individualized.

Please take the following actions:

FOR INVENTORY IN STOCK:

1. Check inventory to determine if you have any directCHECK Whole Blood Control DCJPT-A Lot Number G9DPA005.
2. Immediately discontinue shipment of any product in inventory and place the product on "Hold." Forward this Correction Notice to all those who need to be aware within your organization.
3. Complete the enclosed Distributor Account Tracking Form to indicate the number of boxes of directCHECK Whole Blood Control DCJPT-A Lot Number G9DPA005 you have in inventory. ITC will contact you to make arrangements for you to return the boxes and for replacement boxes to be sent to you.

FOR INVENTORY SHIPPED TO YOUR CUSTOMERS:

1. Send by traceable (certified or other) mail, a Field Safety Notice for each customer that received at least one box of Lot Number G9DPA005.

   Your customers are to keep a copy of this Field Safety Notice with the material and use the correct acceptable performance range listed above instead of the range published on the package insert.

2. Complete the enclosed Distributor Account Tracking Form and confirm that you have notified your customers. Fax or e-mail the completed form to ITC using the contact information number listed.

3. ITC recommends the following for product users:

Review quality control tests performed using the incorrect control range:

(1) If the control test result was 3.7, 3.8, 3.9, or 4.0, the test result was falsely accepted. A patient result reported at that time or since then using the incorrect control range may be invalid. The situation should be reported to Risk Management and the suspect test result(s) should be reviewed with the medical director of the laboratory to determine appropriate follow-up. If not already done, quality control tests with both the normal and abnormal levels of directCHECK should be repeated using the correct control range before reporting any new patient results. Continued use of the test system should be predicated on acceptable quality control along with follow-up actions recommended by the medical director and/or Risk Management.

(2) If the control test result was anything other than 3.7, 3.8, 3.9, or 4.0, no further action need be taken regarding the results.

Please be cognizant that no control system can detect all malfunctions and therefore patient results should always be reviewed on an individualized patient basis.

ITC requests that you contact us immediately if you receive reports from your customers indicating that incorrect treatment decisions or patient impact resulted from use of the incorrect QC range.

NOTE: Only Lot Number G9DPA005 is affected by this correction; no other lots are affected.

Questions?	**If you have questions, please call ITC Technical Support at 732-548-5700, Extension 4707 or email techsupport@itcmed.com**.

directCHECK® DCJPT-A
Lot Number G9DPA005 Correction
RAF #10-008

Please complete and return this form:

Company Name _____

Shipping Address _____
Street

_____
City / Province Country Postal Code

Contact Name _____

Contact Phone Number _____

Fax Number _____ E-Mail Address _____

☐ I have read and understand the attached letter.

1. FOR INVENTORY IN STOCK:

☐ My company has placed all inventory of Lot Number G9DPA005 on "Hold."

☐ My company has the following amount of directCHECK® Whole Blood Control DCJPT-A Lot Number G9DPA005: _____ Boxes.

2. FOR INVENTORY SHIPPED TO CUSTOMERS:

☐ I have notified my customers using the provided Laboratory Communication Packages.

Enter the number of your customers that were shipped directCHECK DCJPT-A Lot Number G9DPA005 product _____

Enter the number of customers you have notified _____

Enter the method you used to notify your customers _____

3. PLEASE PROVIDE YOUR SIGNATURE:

Name (Print) _____ Signature: _____ Date: _____

FAX or E-MAIL to:

ITC Technical Support
20 Corporate Place South
Piscataway, NJ 08854 USA
Telephone: 732-548-5700 Ext. 4707
FAX: 866-429-3132
E-MAIL: **techsupport@itcmed.com**

XX-June-2010

ATTENTION: Laboratory Director, Clinical Laboratory Manager, or Point-of-Care Coordinator

URGENT – Field Safety Notice
directCHECK® Whole Blood Control
DCJPT-A Lot Number G9DPA005
RA10-008

ITC has determined that the directCheck Whole Blood Control, Lot Number G9DPA005, package insert contains the incorrect acceptable performance range for J201 PT cuvettes. Our records indicate that at least one box of this product has been shipped to your facility. The correct control material range is 4.1 – 8.7 INR.

Incorrect Acceptable Performance Range	**Correct Acceptable Performance Range**
3.7 – 6.5 INR	4.1 – 8.7 INR

Use of the control with the incorrect range may falsely accept quality control tests performed on a malfunctioning test system that would otherwise be correctly rejected with use of the correct control range. ITC statistical analysis indicates that the incorrect control range allows up to 13% more false acceptance of quality control tests than does the correct control range. This is important because this PT assay monitors use of Coumadin which is a drug with a narrow therapeutic range and is highly individualized. ITC therefore recommends the following:

Please review quality control tests performed using the incorrect control range:

(1) If the control test result was 3.7, 3.8, 3.9, or 4.0, the test result was falsely accepted. A patient result reported at that time or since then using the incorrect control range may be invalid. The situation should be reported to Risk Management and the suspect test result(s) should be reviewed with the medical director of the laboratory to determine appropriate follow-up. If not already done, quality control tests with both the normal and abnormal levels of directCHECK should be repeated using the correct control range before reporting any new patient results. Continued use of the test system should be predicated on acceptable quality control along with follow-up actions recommended by the medical director and/or Risk Management.

(2) If the control test result was anything other than 3.7, 3.8, 3.9, or 4.0, no further action need be taken.

Please be cognizant that no control system can detect all malfunctions therefore patient results should always be reviewed on an individualized patient basis.

ITC requests that you contact us immediately if you believe any incorrect treatment decisions or patient impact resulted from use of the incorrect QC range.

NOTE: Only Lot Number G9DPA005 is affected by this notice.

Please take the following actions:

1. Check your inventory to determine if you have any directCHECK Whole Blood Control DCJPT-A Lot Number G9DPA005.

2. If you have boxes or loose vials from Lot Number G9DPA005, keep a copy of this Field Safety Notice with the material and use the correct acceptable performance range listed above instead of the range published on the package insert.
3. **IMPORTANT:** Whether or not you have remaining inventory of directCHECK Lot Number G9DPA005, it is important that you complete the attached **Customer Account Tracking Form** and return it by fax or e-mail.

The relevant National Competent Authorities have been advised of this voluntary correction. The Authorized Representative is MDSS GmbH (Telephone: + 49 511 62 62 86 30). Thank you very much for your attention to this matter.

Questions?	**If you have questions, please call ITC Technical Support at 732-548-5700 Extension 4707, or e-mail techsupport@itcmed.com.** **Local Contact Information: Please contact your distributor.**

OUS Customer Account Tracking Form
directCHECK® Whole Blood DCJPT-A Field Safety Notice
Lot Number G9DPA005
RAF 10-008

Please complete and return this form.

Customer Name _____

Customer Address _____
Street

_____
City / Province Country Postal Code

Contact Name _____

Contact Phone Number _____

Fax Number _____ E-Mail Address _____

Please select all that apply:

☐ I have read and understand the attached letter.

☐ I have the following amount of directCHECK Whole Blood Control DCJPT-A Lot Number G9DPA005:

_____ Full Boxes Plus _____ Vials from Opened Boxes

☐ I do not have any directCHECK Whole Blood Control DCJPT-A Lot Number G9DPA005 product.

☐ I was not able to complete the actions provided in the letter because (please describe below):

_____

_____

_____

FAX or E-MAIL to:

ITC Technical Support
20 Corporate Place South
Piscataway, NJ 08854 USA

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FAX: 866-429-3132
E-MAIL: techsupport@itcmed.com