

Important Notice

Product code and description: LK016.RI - Freelite Human Kappa Free Integra Kit

Reference: GLB107001

Action: Correction

Date: 26 February 2016

Issue: Reassignment of LK016.RI lot 355769

Details of affected devices:

Product	Lot number(s)/ software version	Expiry
LK016.RI - Freelite Human Kappa Free Integra Kit	355769	01/2017

Description of the problem:

Through the course of a post-release product investigation, it has been determined that LK016.RI lot 355769 calibrator and controls require a reassignment which is 16% lower than the value established during the manufacture of this product.

The Binding Site confirms that the degree of bias is within the total allowable error for this assay and consequently will have had no impact on patient management.

A correction of the calibrator and QC values has been determined as the responsible course of action. This ensures that results reported based on these revised values will be a more accurate reflection of the free light chain (FLC) value. The change of calibration by 16% is within the natural biological variation of FLC in serum (+/-28%) (*Katzmann et al. 2011*). It is within the +/-20% allowable variability of the assay control values.

Action to be taken by the user:

1. No action is required with regard to patient results previously reported using this kit lot.
2. This kit lot should be recalibrated with the new calibrator value provided in the table below. (Please refer to the revised QC datasheet).

Code	Description	Reassigned Target Value	Reassigned Range
LC016.RI	Calibrator	16.51 mg/L	-
NL016.RI	Low QC	13.02 mg/L	10.42 – 15.62 mg/L
NH016.RI	High QC	26.80 mg/L	21.44 – 32.16 mg/L

3. Re-programme your instrument with the information enclosed in the revised QC Certificate.

Circulations of this Information:

This notice must be distributed to all persons within your organisation who are required to maintain awareness of the notification or to any additional organisation where the aforementioned product has been transferred. Please keep a record of this notice and actions until the expiry of the product, or for an appropriate period.

On behalf of The Binding Site, we apologise for any inconvenience caused and we thank you for your continued custom and support.

Please sign, date and return the Field Correction FaxBack to your local Binding Site representative.

Should you have any questions in this regard please contact your local Binding Site representative.


David McConville
Technical Services Manager

The Binding Site Group Ltd


Hugh Carr-Smith
Technical Director

The Binding Site Group Ltd

Product Data Sheet for Human Kappa Free kit (for use on the Cobas® Integra*)

Kalibrator-/Kontrolldatenblatt für Kappa Freies (Human) Kit (zur Verwendung auf dem Cobas® Integra)(D)
 Données calibrateurs/contrôles pour le coffret de dosage des Kappa Libres Humains (pour utilisation sur Cobas® Integra)(F)
 Hoja de datos del producto para el kit Kappa Free Humano (para el uso en el Cobas® Integra)(E)
 Ficha de segurança para o kit para o doseamento de Kappa livre humana (para utilização no Cobas® Integra)(P)
 Scheda del Prodotto per il kit Kappa Free Umano (per uso su Cobas® Integra)(It)
 Příbalový list soupravy na stanovení volného lidského řetězce Kappa (na analyzátoru Cobas® Integra) (Cz)
 Kalibrator-/Kontrolltablad för Human Kappa Fria lätta kedjor kit (för användning med Cobas® Integra)(S)
 Produkt information for Human Kappa Free kit (til anvendelse på Cobas® Integra) (Dk)

PRODUCT CODE / BESTELL-NR / REFERENCE DU PRODUIT / CÓDIGO PRODUCTO / CÓD. PRODUCTO / CODICE PRODOTTO / KÓD VÝROBKU / PRODUKTNUMMER / PRODUKTKODE	LK016.RI
Batch Number / Batch-Nr / Numéro de lot / Número lote / Lote / Numero lotto / Číslo šarže / Batchnummer / Batchnummer	355769
Expiry / Verfallsdatum / Date de péremption / Fecha de caducidad / Validade / Data di scadenza / Datum expirace / Utgångsdatum / Udløbsdato	2017 / 01
CALIBRATOR/ KALIBRATOR / CALIBRATEUR / CALIBRADOR / CALIBRADOR / CALIBRATORE / CALIBRATOR / KALIBRATOR / KALIBRATOR	
Calibrator Code / Kalibratorcode / Référence du calibrateur / Código calibrador / Cod. Calibrador / Codice calibratore / Kód kalibrátoru / Kalibratorproduktnr / Kalibratorkode	LC016.RI
Calibrator Batch / Kalibratorcharge / Lot du calibrateur / Lote del calibrador / Lote do calibrador / Lotto calibratore / Šarže kalibrátoru / Kalibratorbatch / Kalibratorbatch	355033
Expiry / Verfallsdatum / Date de péremption / Fecha de caducidad / Validade / Data di scadenza / Datum expirace / Utgångsdatum / Udløbsdato	2017 / 01
Calibrator Value / Kalibratorzielwert / Concentration du calibrateur / Valor del calibrador / Valor do calibrador / Valore calibratore / Hodnota kalibrátoru / Kalibratorvärde / Kalibratorværdi	16.51 mg/L

Product Data Sheet for Human Kappa Free kit (for use on the Cobas® Integra*)

KIT CONTROLS/ KIT KONTROLLEN / CONTROLES DU COFFRET / CONTROLES DEL KIT / CONTROLOS / CONTROLLI DEL KIT / KONTROLY SOUPRAVY / KITKONTROLLER / KIT KONTROL		
Control / Kontrolle / Contrôle / Control / Controllo / Kontrola / Kontroll / Kontrol	Low/ Low / Bas / Bajo / Baixo / Basso / Nizká / Låg / Lav	High / High / Haut / Alto / Elevado / Alto / Vysoká / Hög / Høj
	NL016.RI	NH016.RI
Control Batch/ Kontrollcharge / Lot du contrôle / Lote control / Lote de controllo / Lotto controllo / Šarže kontroly / Kontrollbatch / Kontrolbatch	355034	355035
Expiry/ Verfallsdatum / Date de péremption / Fecha de caducidad / Validade / Data di scadenza / Datum expirace / Utgångsdatum / Udløbsdato	2017 / 01	2017 / 01
Control value / Kontrollzielwert / Concentration du contrôle / Valor del control / Valor do controllo / Valore del controllo / Hodnota kontroly / Kontrollvärde / Kontrollværdi	13.02 mg/L	26.80 mg/L
Assigned SD/ Zugewiesene Standardabweichung (SD) / Coefficient de corrélation assigné / SD asignado / Desvio do padrão atribuído / DS assegnata/ Zadaná standardní odchylka / Tilídelad SD / Tildelt SD	1.30 mg/L	2.68 mg/L
Control range/ Kontrollbereich / Gamme du contrôle / Rango del control / Intervalo de controllo / Range del controllo / Rozsah kontroly / Kontrollintervall / Kontrol intervall	10.42 - 15.62 mg/L	21.44 - 32.16 mg/L
All concentrations are in mg/L. / Alle Konzentrationsangaben sind in mg/L / Toutes les concentrations sont en mg/L / Todas las concentraciones son en mg/L / As concentrações estão representadas em mg/L / Tutte le concentrazioni sono in mg/L / Všechny koncentrace jsou v mg/L / Alla koncentrationer är i mg/L / Alle koncentrationer er i mg/L		

*Cobas® Integra is a registered trademark of the Roche group, Mannheim, Germany. / Cobas Integra® ist eingetragenes Warenzeichen von Roche Diagnostics GmbH, Deutschland. / Cobas Integra® est une marque déposée du groupe Roche, Allemagne. / Cobas Integra® es una marca registrada del grupo Roche, Alemania. / Cobas Integra® é uma marca registrada do Grupo Roche, Alemanha. / Cobas Integra® è un marchio registrato dal gruppo Roche, Germania. / Cobas Integra® je registrovaná ochranná známka skupiny Roche, Německo / Cobas® Integra är ett registrerat varumärke som tillhör Roche-koncernen, Mannheim, Tyskland / Cobas® Integra II er et registreret trademark for Roche-koncernen, Mannheim, Tyskland

Kit Reagents are lot specific and are not interchangeable. / Die Kitkomponenten sind chargenspezifisch. Reagenzien unterschiedlicher Chargen dürfen nicht untereinander gemischt werden. / Les composants du coffret sont spécifiques du lot et ne sont pas interchangeables. / Os componentes do kit são específicos para este lote y no son intercambiables. / Os componentes dos kits são específicos de cada lote, não podendo ser trocados entre lotes diferentes. / I componenti del kit sono lotti specifici e non sono intercambiabili. / Komponenty soupravy jsou specifické pro danou šarži a nejsou zaměnitelné. / Kit reagenser är lot specifika och är INTE utbytbara / Kit Reagenser er lot specifikke og kan ikke udskiftes med andre lots