المركز الوطني للبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Safety Communication

Risk of Inaccurate Results

Device/ Product Description:	Hematology Analyzers
Brand Name:	UniCel DxH 800/600/900 Coulter Cellular Analysis System
Lot numbers/Serials:	All software versions
Manufacturer:	Beckman Coulter
Problem:	Complaints of erroneously elevated platelet results, without flags or system messages. The underlying issue is temporary disturbance of the sweep flow. Preliminary root cause investigation indicates that sweep flow disruption may occur following the Clear RBC Apertures procedure. The issue may affect one or multiple samples tested in sequence. Inaccurate platelet counts may cause serious adverse health consequences.
Recommendation/Actions:	1. Follow the instructions in the notification letter until further notice 2. Discontinue using “Clear RBC Aperture” procedure until further notice. You can read the complete Safety Alert that includes recommendations from (HERE). In addition, more information could be helpful in this link.

Devices/Products photo:	

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

Healthcare Professionals should **report any adverse events** suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority
4904 northern ring branch rd - Hitteen Dist.
RIYADH 13513 - 7148
Tel: +966 (11) 2038222 Ext: 2406, 2479
Fax: +966 (11) 2757245
Or
Saudi Vigilance

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team