



Circular No. 15 / 2022

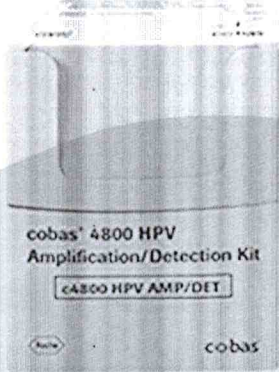
بمقدم
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21 -01-1443 H

24 -06-2022

Recall of Kit Cobas 4800 HPV AMP/DET from Roche Diagnostics Middle East.

Source	GHC-Gulf Health Council.
Product	<ul style="list-style-type: none">Cobas® 4800 HPV Amplification / Detection Kits.KIT Cobas 4800 HPV AMP/DET 240T CE-IVD.
Manufacturer	Roche Diagnostics Middle East.
Local Agent	National Pharmacy LLC.
The affected products	<ul style="list-style-type: none">H09804: KIT cobas 4800 HPV AMP/DET.H05627: KIT cobas 4800 HPV AMP/DET 240T CE-IVD.
Reason	Roche discontinuing the use of above lots because they may not be performing as intended, and may result in invalid result. The issue is limited to the beta globin target, no other targets are affected.
Action	<ol style="list-style-type: none">Discontinuing the use of above lots.For invalid sample results, test to be repeated using original specimen.Contact the local agent for remedial action.
Product Picture	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

/Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL





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To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 15/2022 dated 22/11/2022. Regarding GHC recall of Kit Cobas 4800 HPV AMP/DET from (mrf: Roche Diagnostics Middle East.).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧٨٨ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489

dgpa_dc Email: dg-padc@moh.gov.om



تقارير السلامة للأجهزة والمستلزمات الطبية
Safety Alerts of Medical Device Products

To: HE / Members of the Executive Committee of the Cooperation Council States Members	إلى: سعادة/ أعضاء الهيئة التنفيذية بدول مجلس التعاون.	
Subject:	تحذير سلامة لمنتج طبي (KIT cobas 4800 HPV AMP/DET) من إنتاج شركة (Roche Diagnostics Middle East)	الموضوع:
Product Name:	<ul style="list-style-type: none">Cobas® 4800 HPV Amplification / Detection KitsKIT cobas 4800 HPV AMP/DET 240T CE-IVD	اسم المنتج:
Company:	Roche Diagnostics Middle East	الشركة:
Affected product:	H09804 - H05627	المنتجات المتأثرة:
Reg. Status in GHC:	Not registered	وضع المنتج في مجلس الصحة:
Source of Warning:	Roche – MOHAP UAE	مصدر التحذير:
Reason for Warning:	أفادت وزارة الصحة ووقاية المجتمع أن سبب التحذير هو قيام الشركة بسحب التشغيلات المذكورة أعلاه لأنها لا تعمل على النحو المطلوب، بحيث قد تؤدي إلى نتائج غير صحيحة، وتقتصر المشكلة على (Beta glo bin target) فقط.	سبب التحذير:
Recommendation:	أوصت وزارة الصحة ووقاية المجتمع بما يلي: <ul style="list-style-type: none">التوقف عن استخدام التشغيلات المذكورة أعلاه.يجب إعادة الاختبار باستخدام العينة الأصلية عند وجود نتائج غير صحيحة.	التوصيات:
Link of Circular	يرجى الاطلاع على التعميم المرفق	رابط التعميم:
For inquiries and reporting:	pms@ghc.sa	للاستفسارات والإبلاغ: