



To:

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
Commanding Officer, Armed Forces Hospital (Al Khouth & 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**

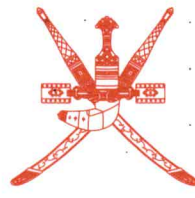
After Compliments,

Please find attached our Circular No. 36 ..... dated 17/2/22 Regarding NCMDR recall of ImmunoPass , COVID-19 Neutralizing Antibody Test, NAB 900-60 from ( mrf: Empowered Diagnostic LLC).

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





Circular No. 36 / 2022


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17 -02-2022

لنقدم بثقة  
Moving Forward  
with Confidence



**Recall of ImmunoPass , COVID-19 Neutralizing Antibody Test, NAB 900-60 from Empowered Diagnostic L**

Source	FDA-Food & Drug Administration <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=191254">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=191254</a>
Product	ImmunoPass , COVID-19 Neutralizing Antibody Test, NAB 900-60.
Description	Reagent, coronavirus serological - Product Code QKO.
Manufacturer	Empowered Diagnostics LLC.
Affected	all lots.
Reason	COVID test kits were offered for sale and distributed to consumers in the United States without marketing approval, clearance, or authorization from FDA.
Action	1. Discontinuation of use and distribution. Those who has further distributed the products, were requested to conduct a sub-recall. 2. Contact the local agent for remedial action.
Product Image	
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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

  
Dr. Mohammed Hamdan Al Rubaie  
DIRECTOR GENERAL

