Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Devices Division)

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002

File No. 29/Misc/3/2012-DC (09) **Date:** 13 JUL 2012

To,

All Zonal /Sub-Zonal/ port Offices of CDSCO

SUB: Clarification regarding NOC for import of 1.raw material for diagnostic kits/ reagents and 2.diagnostic kits/ reagents for Research Use Only (RUO) etc. - Reg.

Sir,

It is to clarify that as per current practices:

1 .Raw materials for diagnostic kits and reagents which are further used in the manufacturing of the finished In-vitro Diagnostic Kits and

2. In- Vitro diagnostic kits / reagents /Samples intended for Research Use Only, for the purpose of Accreditation / Certification of Hospital/ Laboratories like College of American Pathologists (CAP) Accreditation, etc and for External Quality Assurance Scheme (EQAS) during import ,

are not being regulated under provision of Drugs & Cosmetic Act and Rules(through Form 10 or Form 11 etc.).

Therefore, such cases may be examined and released at the level of ADC (I)/ Incharge/port officer without referring for NOC.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)