

## \* Reagents & consumable requirement.

- Documented procedure for reception, storage, acceptance testing & inventory management.
- Store received reagents & consumables according to manufacturer's specification.
- Verify for performance before use - each new formulation of examination kits with changes in reagent or procedure or a new lot or shipment for acceptance testing.
- Instruction for use of reagent & consumables including provided by manufacturer shall be available.
- Report adverse incident & accident to manufacturer & appropriate authorities if required.
- Records for each reagent & consumable shall be maintained, & it includes
  - 1- Identity of reagent or consumable
  - 2- manufacturer's name & batch code or lot number
  - 3- Contact information for supplier or manufacturer.
  - 4- Date of receiving, expiry date, date of entering into services, where applicable - the date the material was taken out of service.
  - 5- condition when received [acceptable or damaged]
  - 6- Manufacturer's instruction
  - 7 - Records that confirmed reagents or consumables ongoing acceptance for use.

6 - performance records that confirm reagents or consumables ongoing acceptance for use.

In case of reagent prepared or completed in house → also includes reference to person or persons undertaking their preparation  
date of preparation.