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Q. Process of introducing new method in routine use:- / Method selection:-

involves ① medical need
② Analytical performance criteria
③ Practical criteria

→ flow diagram of process of introducing new method in routine use.

Medical need
↓
Define quality goal
↓
Method select^{n} / Development
↓
Method verification / validation
↓
Implementation
↓
Routine analysis
↓
QC practices
↓
Result report.

① Medical Need:-

- Optimal patient care
- Advance in patient care.

} → based on new or improved lab. te

→ Communication b/w. laboratorian and clinicians required acquired

↓ for

to desire parameters like

- TAT
- clinical utility of assay
- total allowable error of assay
- ~~detection limit~~

→ Already established analyte

↓

replacement of older, labor-intensive method & new, automated assay

↓

is more economical, sufficient precision, accuracy, analytical measurement range, and no interference → Ex- Ca^{2+} by ocpc and arsenazo

② Analytical performance criteria and defining quality goal

→ evaluation of performance characteristics like

precision

accuracy

Analytical range

Detection limit

↓

All parameter are related to quality goal. ~~to~~ ensures medical use of test results.

q. goals → ① EQAS, RQC & in 2SD

② CLIA criteria

③ CLSI guideline

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③ Validation and Verification of method.

* Validation - process of establishing sample processing, reagent, volume, pH, temp, sensitivity, specificity, linearity of method.

↓

~~Verifies~~

Confirmation that specific req. met for intended use is fulfilled through objective evidence.

* Verification :-

rechecking various specification used for new method are validated

④ ~~plan~~ :

⑤ other practical criteria :-

→ When prospective method reviewed, attention should be given to

(1) Principle of assay
(2) Detailed protocol performing test
(3) Reagent and Ref. material
   ↳ composition, quantity provided, storage
(4) Stability of Reagent and Ref. material
(5) Technologist time and skill req.
(6) possible hazards and safety precaution

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(7) Type, quant and disposal of waste generated.
(8) Specimen requirement.
- collect" and transportation.
- Volume req.
- Anticoagulants / preservatives req.

(9) Instrumental req. and limitations
(10) Cost effectiveness
(11) Computer platform and LIS.

(5) plan the implementation

(6) Introduce routein analysis

(7) Daily quality control and reporting of results

(8) Reevaluation whether the purpose is served.