Future perspectives in quality assurance

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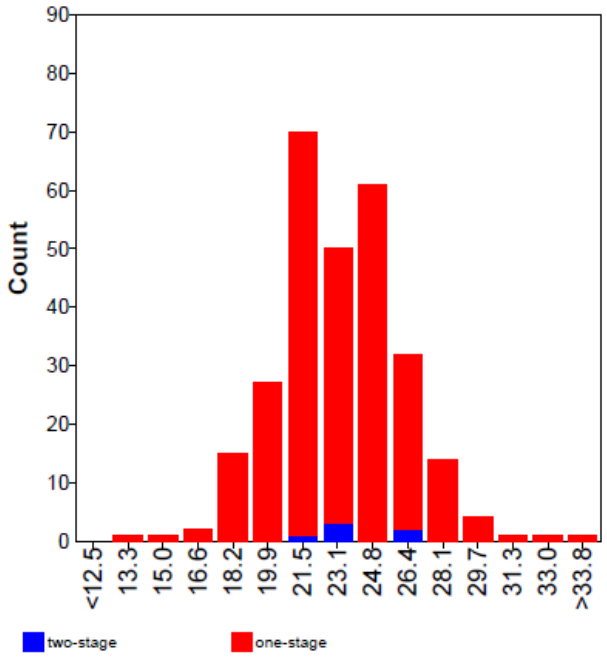
Regular EQA approach ⇨ Consensus value



	N	Assigned Value (IU/dL)	CV (%)	Range
Total group	280	23	11.5	13 - 36

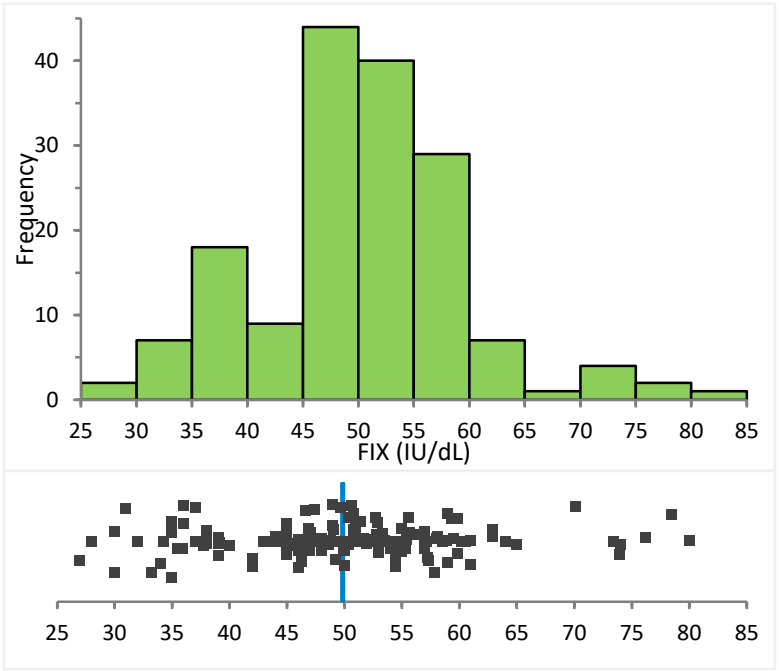
Lab result : 26 IU/dL

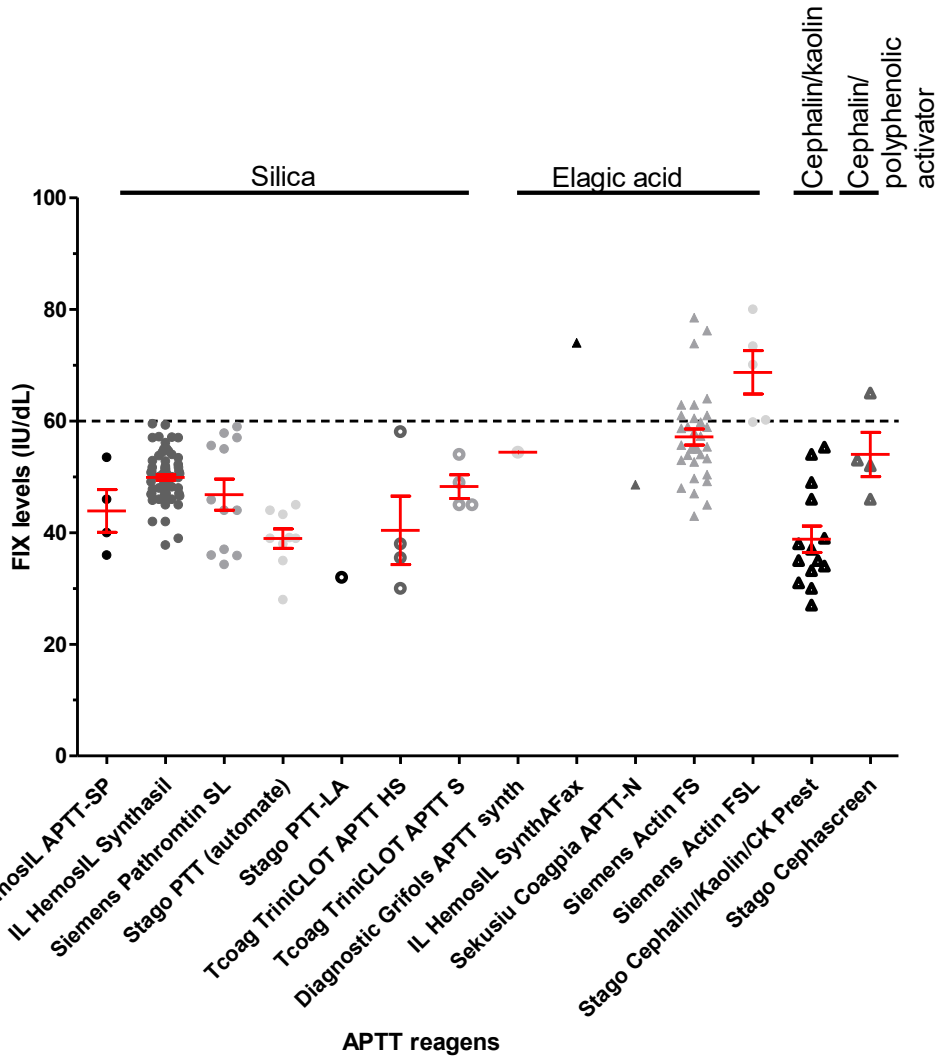
Z- score : (26-23)/2.65 = 1.13

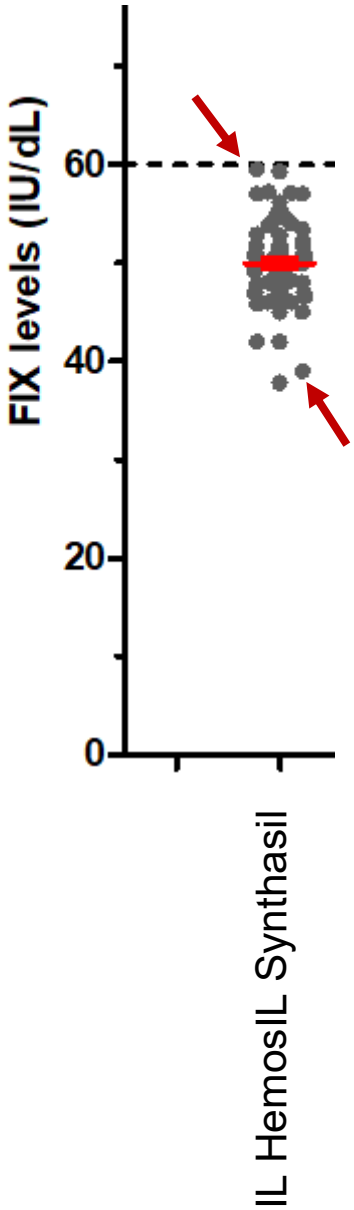
% Deviation : [(26-23)/23]*100% = 13.0%

Is this approach suitable for performance assessment with extended half-life product samples?

Example: Alprolix (60 IU/dL)







Target : 60 IU/dL

Consensus : 49.8 IU/dL

Result : 60 IU/dL
Result : 40 IU/dL

% Deviation	40 IU/dL	60 IU/dL
Consensus	- 19.7%	20.5%
Target	- 33.3%	0.0%

EQA approach for drug monitoring

- Performance assessment with respect to the target value
- Drug recovery
- Target value on the basis of potency labelling

Questionnaire on interest for EQA surveys for extended half-life FVIII and FIX products.

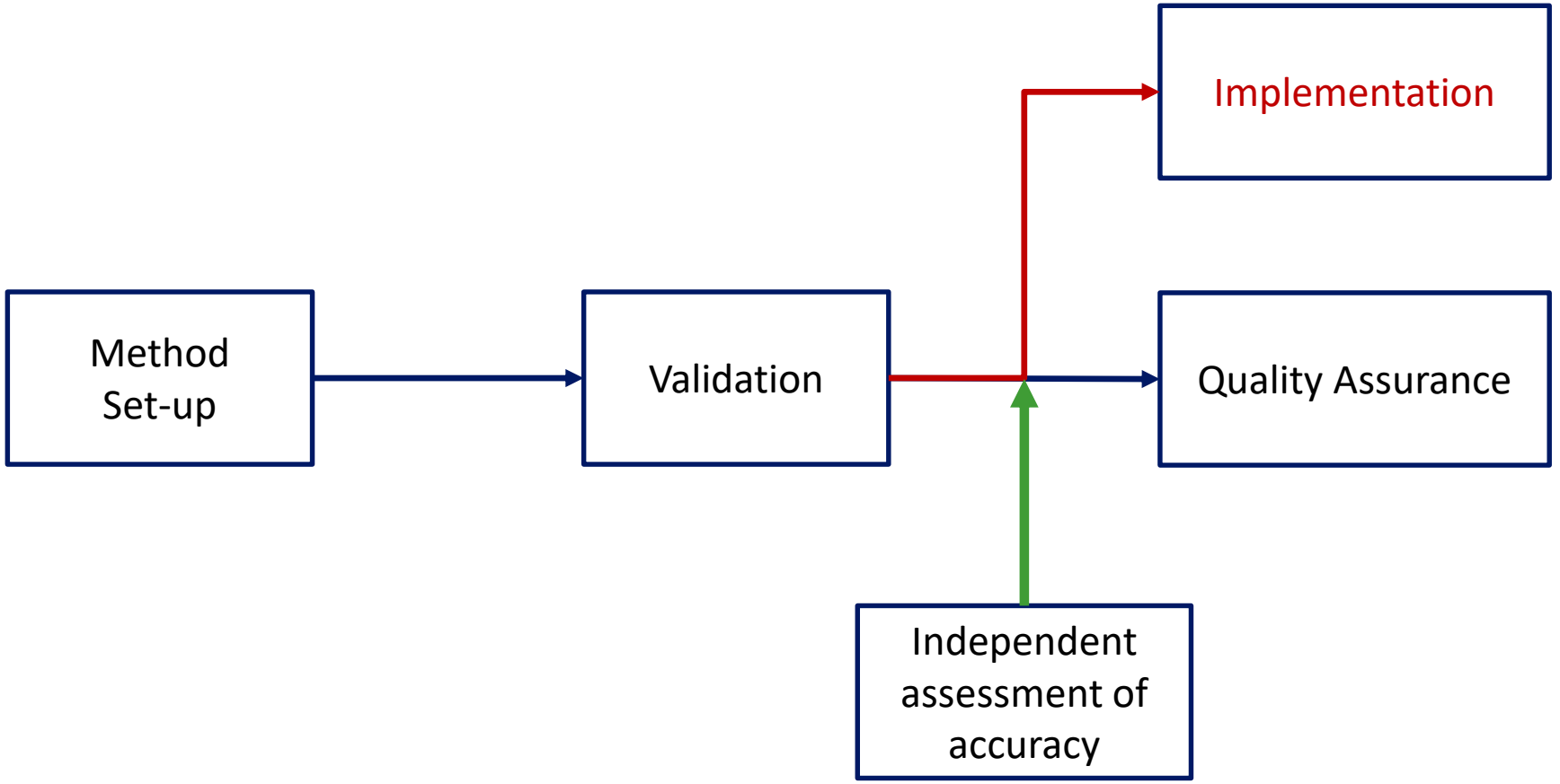
Number of responders : 157

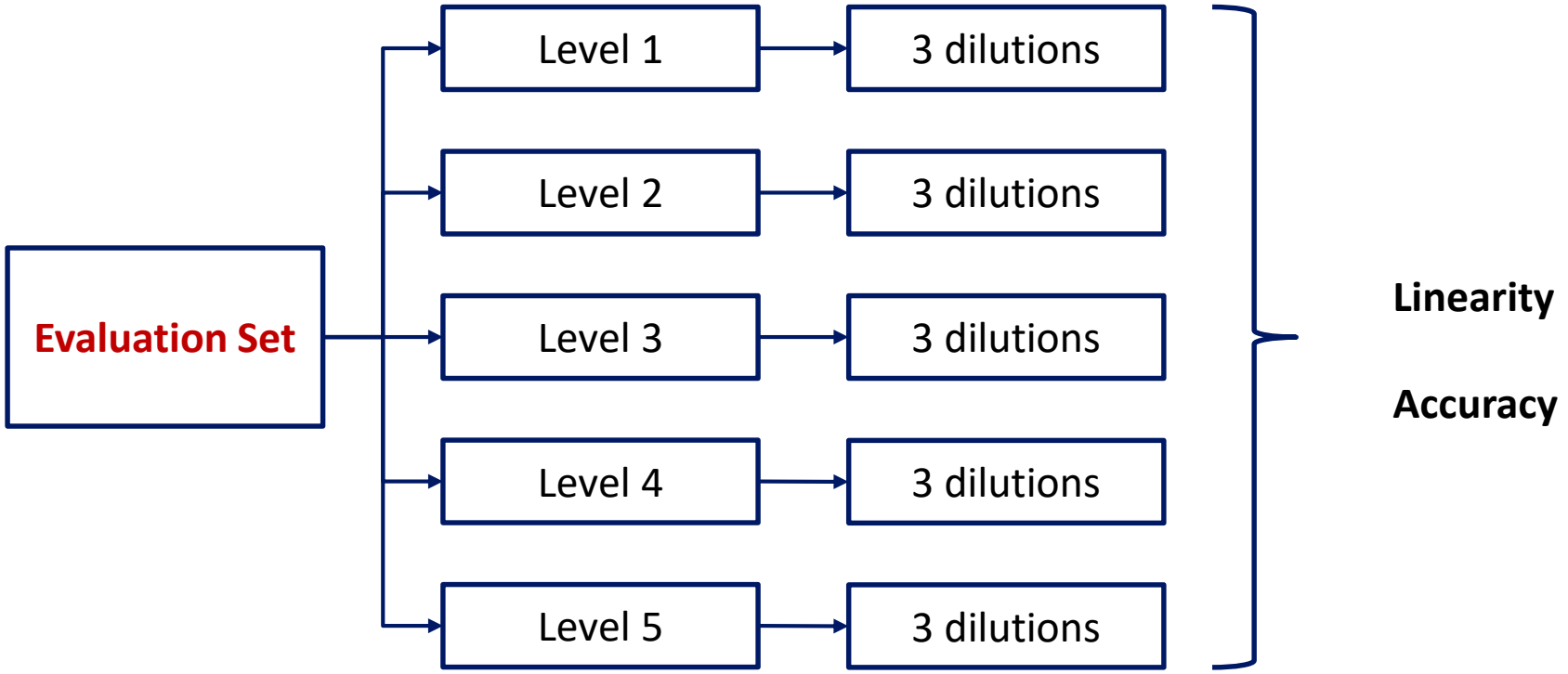
- 27% is interested in specific surveys for EHL products.
- 65% prefer product-specific surveys / 35% unknown samples

Validation

Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

ISO 15189


Implementation
Method
Set-up
Validation
Quality Assurance
Independent
assessment of
accuracy


Evaluation Set
Level 1
3 dilutions
Level 2
3 dilutions
Level 3
3 dilutions
Level 4
3 dilutions
Level 5
3 dilutions
Linearity
Accuracy

Assay Project BAY 94-9027

			Uncertainty	
QC Sample	Target (IU/mL)	Actual Value (IU/mL)	Low	High
1	0.05	0.05	0.048	0.054
2	0.1	0.12	0.113	0.123
3	0.25	0.26	0.242	0.282
4	0.5	0.49	0.454	0.526
5	1.5	1.40	1.290	1.506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· EQA Survey Schedule 2018
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· Assay Project BAY94-9027
· Accreditation
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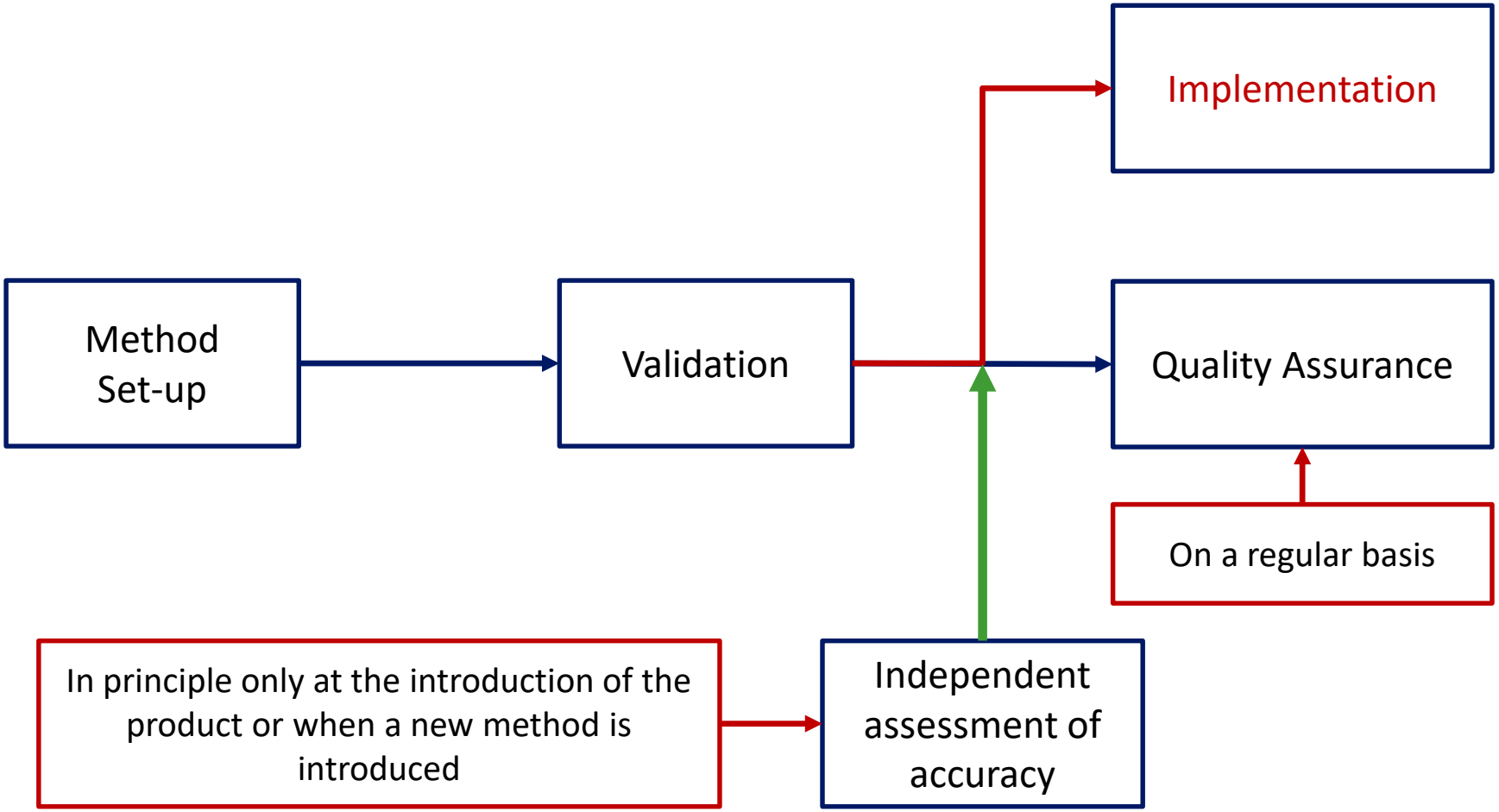
Assay Project BAY94-9027:
BAYER
BAY 94-9027 is a Site-Specifically PEGylated B-Domain-Deleted Recombinant FVIII which has demonstrated safety and efficacy in more than 5 years of clinical studies.
Because BAY 94-9027 is a modified molecule, there is the potential for differences in performance when it is measured in certain coagulation assays established for standard FVIII products. To support medical laboratories in their the need for BAY 94-9027 assay performance information, Bayer has entered into a partnership with North American Specialized Coagulation Laboratory Association (NASCOLA) and External quality Control for Assays and Tests (ECAT) to develop BAY 94-9027 quality control samples for proficiency evaluation and further data collection on assay performance in the coagulation testing community.
The Evaluation Sample Sets contain BAY 94-9027 active pharmaceutical ingredient (API) spiked into FVIII depleted human plasma at 5 different target concentrations from 0.05 IU/mL to 1.5 IU/mL. The individual BAY 94-9027 QC sample vials are lyophilized for reconstitution with 2 mL of water prior to potency testing. Laboratories are requested to measure these samples in multiple dilutions with either one-stage clotting assay and/or a chromogenic assay according to their regular laboratory protocol. Results and detailed information about the methodology used are returned to ECAT using a standard report form. Laboratories will receive a report after evaluation of their results.
Laboratories interested in participation in this project can obtain one Evaluation Set free-of-charge.
Instructions for testing and reporting of data are included in shipment.
To order a BAY 94-9027 Evaluation set complete to order form:
Order form BAY94-9027 Evaluation Set
This is the order form for the BAY94-9027 Evaluation Set.
* mandatory field


Implementation
Method Set-up
Validation
Quality Assurance
On a regular basis
In principle only at the introduction of the product or when a new method is introduced
Independent assessment of accuracy

Future perspectives in quality assurance:

- Surveys for drug monitoring
- Support in method validation
- Education