



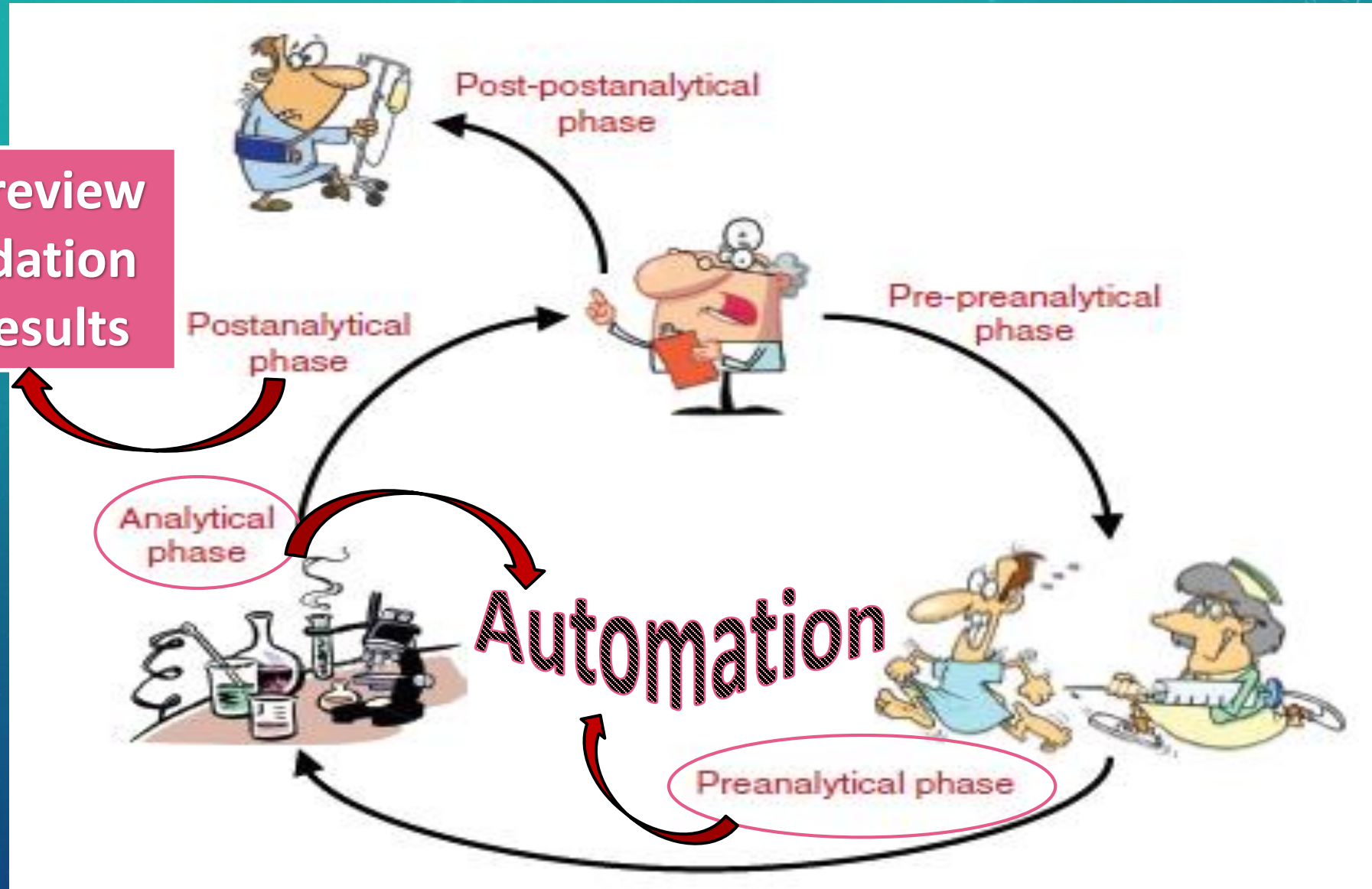
AUTOVALIDATION OF COAGULATION TEST RESULTS

Désirée Coen Herak

Department of Laboratory Diagnostics

University Hospital Centre Zagreb, Zagreb, Croatia

Automation of the total testing process





Postanalytical
phase

AUTOVALIDATION

What is autovalidation?

Autovalidation is an algorithm-based process for the validation of test results that performs results checking according to established and verified criteria.

The most challenging task is to:

DESIGN A COMPREHENSIVE AUTOVALIDATION ALGORITHM

AUTOVALIDATION OF COAGULATION TEST RESULTS

Building and Evaluating the Autoverification of Coagulation Items in the Laboratory Information System

Ying Zhao, Li Yang, Gaozhe Zheng, Yingmu Cai

Clin Lab. 2014;60(1):143-50.

Autovalidation rates in an outpatient coagulation laboratory

P. FROMM, E. SAFFURI-ELIAS, M. BARAK

© 2015 John Wiley & Sons Ltd, *Int. Jnl. Lab. Hem.* 2015;37:380-5.

SCANDINAVIAN JOURNAL OF CLINICAL AND LABORATORY INVESTIGATION, 2016
<http://dx.doi.org/10.1080/00365513.2016.1200135>



Taylor & Francis
Taylor & Francis Group

SHORT COMMUNICATION

Autoverification of routine coagulation assays in a multi-center laboratory

Liselotte Onelöv^a, Elisabeth Gustafsson^a, Eva Grönlund^a, Helena Andersson^a, Gisela Hellberg^a, Ingela Järnberg^a, Sara Schurow^a, Lisbeth Söderblom^a and Jovan P. Antovic^{a,b}

^aDepartment of Coagulation Research, Institute for Molecular Medicine and Surgery, Karolinska Institutet, Stockholm, Sweden; ^bDepartment of Clinical Chemistry, Karolinska University Hospital, Stockholm, Sweden

2016;76:500-2.

WHAT DO YOU NEED FOR THE IMPLEMENTATION OF AUTOVALIDATION OF COAGULATION TEST RESULTS?

**AUTOMATED RERUN
and REFLEX TESTING**

**SEND ALL TEST ORDERS,
AUTOVALIDATE TEST RESULTS
and SEND TEST RESULTS**

**predefined
instructions**



The Ideal Laboratory Information System

Jorge L. Sepulveda, MD, PhD; Donald S. Young, MD, PhD

(Arch Pathol Lab Med. 2013;137:1129-1140)

OUR AUTOVALIDATION STORY



Implementation of the Autovalidation Algorithm for Clinical Chemistry Testing in the Laboratory Information System

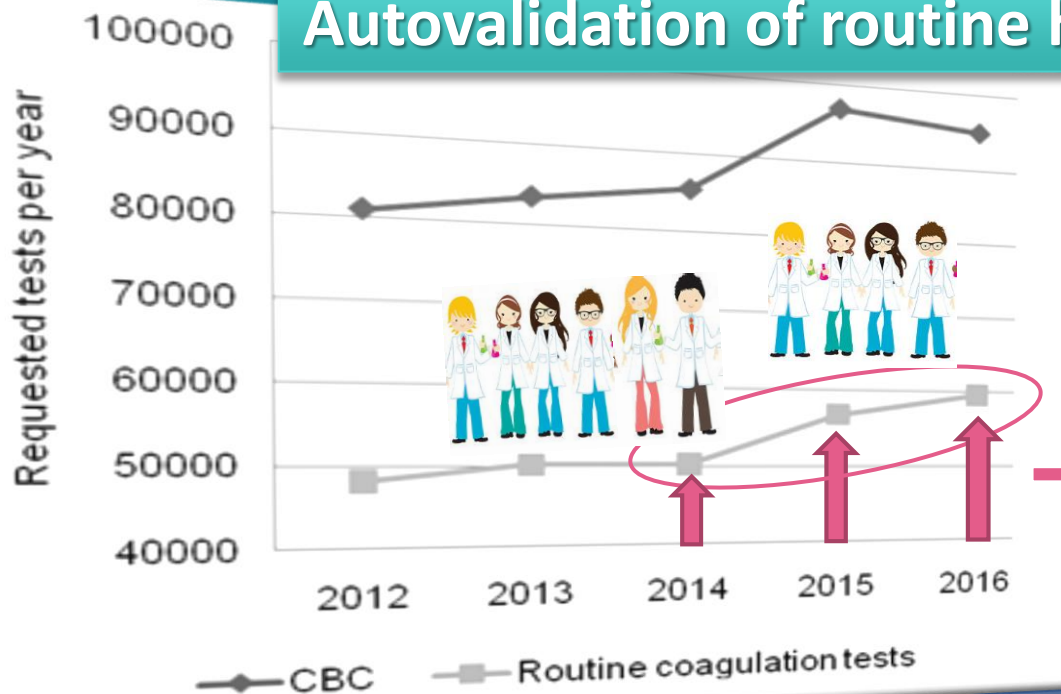
Vladimira Rimac, MD,^{1*} Ivana Lopic, MD,² Kresimir Kules, MD,³ Dunja Rogic, PhD,² Marijana Miler, MD⁴

Laboratory Medicine 2018;00:1-7

implemented in
August 2014

implemented in
December 2015

Autovalidation of routine hematology test results



Autovalidation of
routine coagulation
test results

PT	PT-INR	
FIB	APTT	
	TT	AT

DESIGNING A CUSTOM-MADE COAGULATION AUTOVALIDATION ALGORITHM

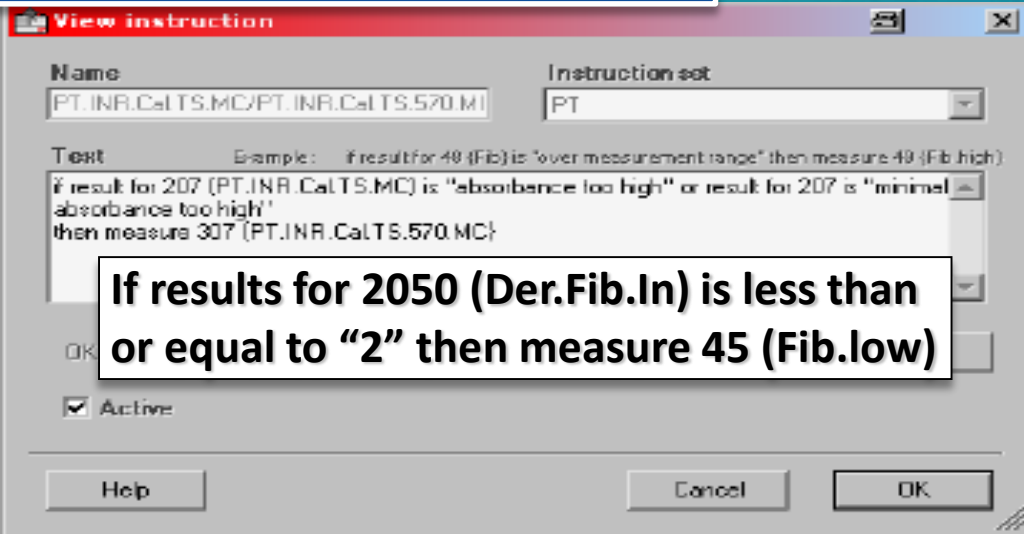
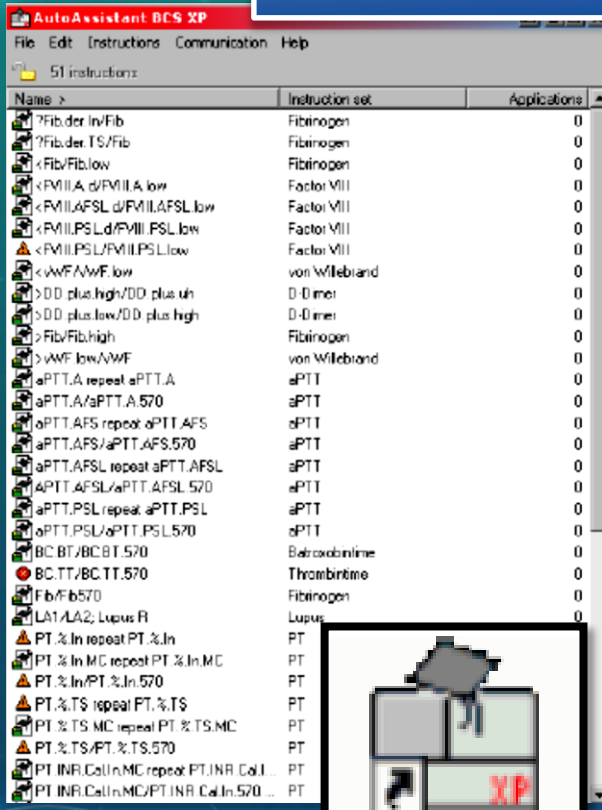


Auto Assistant structured instructions

Define additional laboratory-specific instructions

If results for 2050 (Der.Fib.In) is less than or equal to "2" then measure 45 (Fib.low)

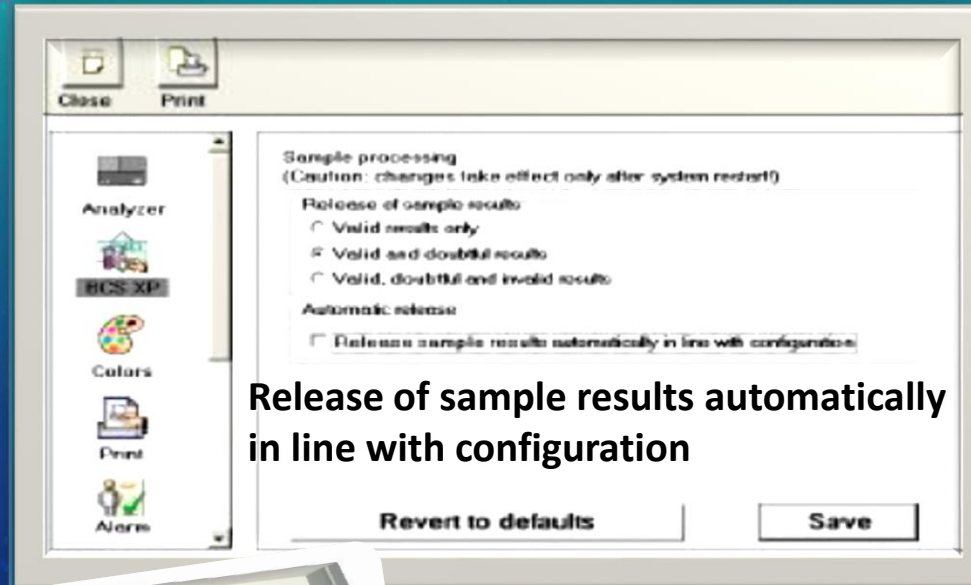
to achieve the highest possible rate of automation



DESIGNING A CUSTOM-MADE COAGULATION AUTOVALIDATION ALGORITHM

Automatic release of sample results:

- valid results only
- valid and doubtful results
- valid, doubtful and invalid results



Release of sample results automatically in line with configuration

Automatic release of **VALID RESULTS ONLY**



Analyzer flags

AUTOVALIDATION ALGORITHM

AUTOVALIDATION RANGE

*(panic values, measurement limit,
values suspected for interferences)*

ANALYZER FLAGS

DELTA CHECK



LIS-BASED AUTOVALIDATION RULES

AUTOVALIDATION RANGE

- range of values that can be reported automatically for a specific test

DELTA CHECK

- used to detect changes in the patient's conditions by comparing a patient's current result with the previous one in a defined time frame
- can be defined in different forms:
 - delta % change or delta difference
 - rate % change or rate difference
 - reference change value (RCV) of each selected laboratory test

$$RCV = (2)^{1/2} * Z_p * (CV_A^2 + CV_i^2)^{1/2}$$

Z_p - number of SD; CV_A – analytical imprecision;
CV_i - within subject biological variation

Ana Mlinaric*, Marija Milos, Désirée Coen Herak, Mirjana Fucek, Vladimira Rimac, Renata Zadro and Dunja Rogic

Autovalidation and automation of the postanalytical phase of routine hematology and coagulation analyses in a university hospital laboratory

Test (reported units)	Autovalidation range		Explanation	Delta check, %/ Time period, days	Analyzer flag ^a /Additional criteria ^b
	Lower level	Higher level			
PT (proportion)	0.14	NA		15/15	NA
PT-INR	NA	4.00		15/15	NA
APTT, s	22	40		13/15	In the presence of no reaction (flat curve) flag, no result nor flag is transferred to LIS
Fibrinogen, g/L inpatients	1.8	7.1	Derived fibrinogen is measured for inpatients by default. If derived fibrinogen is <2.0 g/L or if PT is doubtful, then modified Clauss method is measured	30/15	^a Flag is sent to LIS if: (a) derived fibrinogen is <2.0 g/L; (b) the result for derived fibrinogen is doubtful
Fibrinogen, g/L outpatients	1.8	7.1	Fibrinogen by modified Clauss method is measured for outpatients by default	30/15	NA
AT, %	50	125	Higher level was set as the highest calibrator value	24/15	NA
TT, s	10	30		15/15	NA

AUTOVALIDATION RATES

- great variations depending on the setting and implemented autovalidation criteria:

Patients population included

- **Outpatients only: 96.9%**
Froom P et al. IJLH 2015; 37: 380-5.
- **Both inpatients and outpatients: 55 – 85%**
Onelov L et al. Scand J Clin Lab Invest 2016; 76: 500-2.
- **Both inpatients and outpatients: 65%**
Mlinaric et al. Clin Chem Lab Med 2018; 26: 454-62.

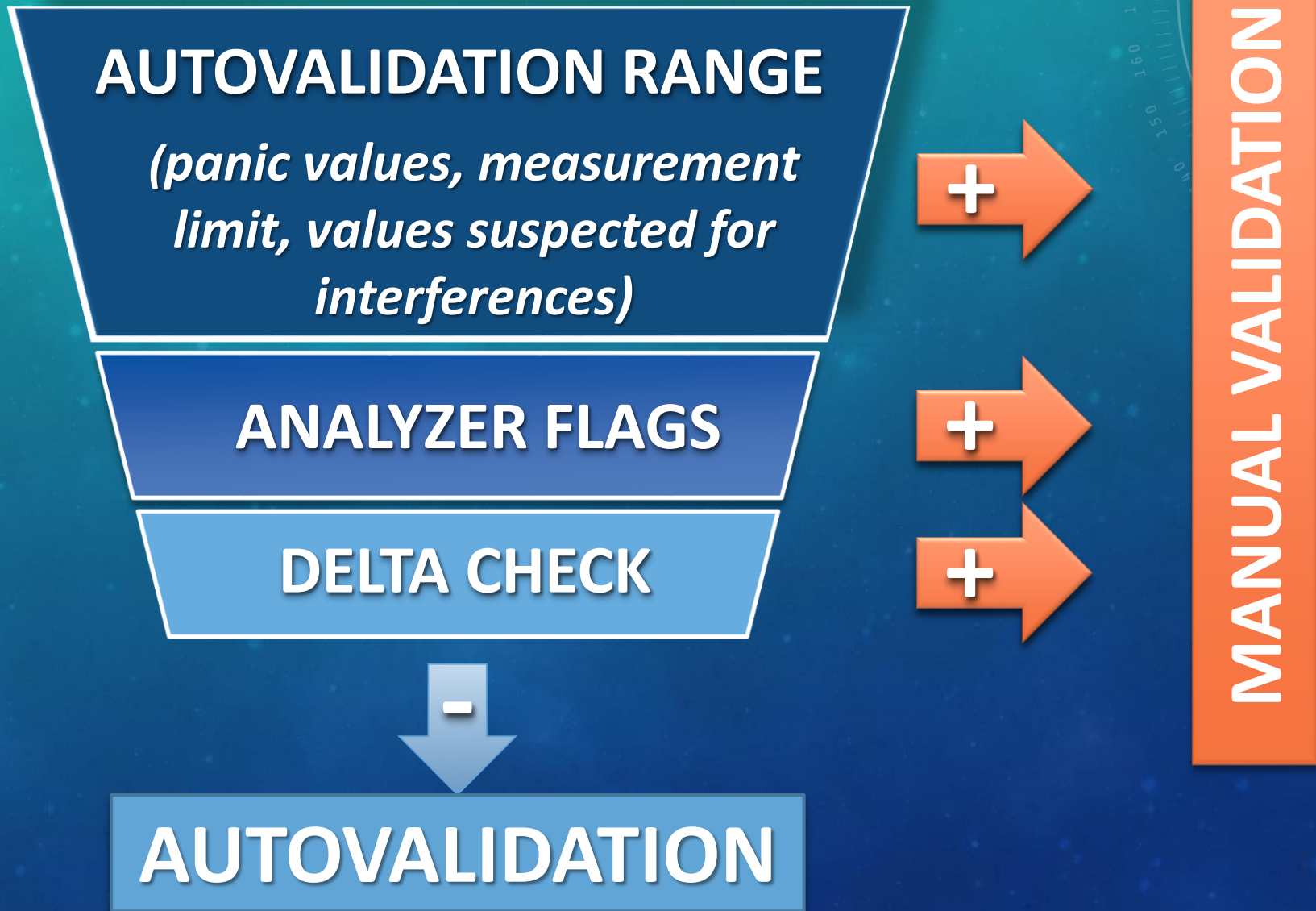
Autovalidation ranges

INR
 ≥ 4.0
 ≥ 5.0
 ≥ 6.0

Delta check time period

- **90 days**
Onelov L et al. Scand J Clin Lab Invest 2016; 76: 500-2.
- **15 days**
Mlinaric et al. Clin Chem Lab Med 2018; 26: 454-62.

AUTOVALIDATION ALGORITHM



VERIFICATION OF AUTOVALIDATION CRITERIA



ISBN 1-56238-620-4
ISSN 0273-3099

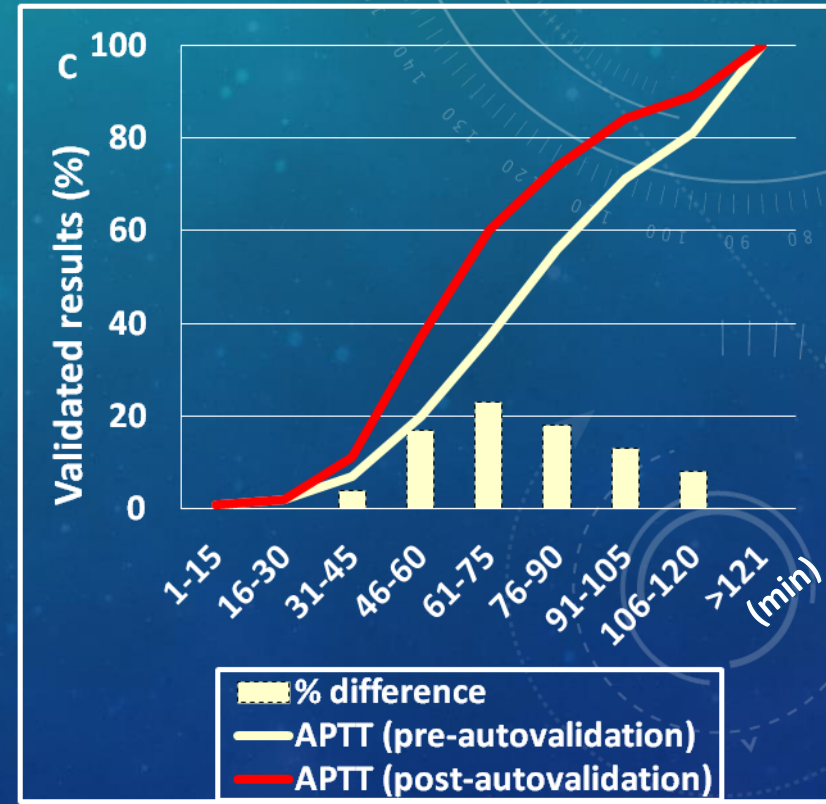
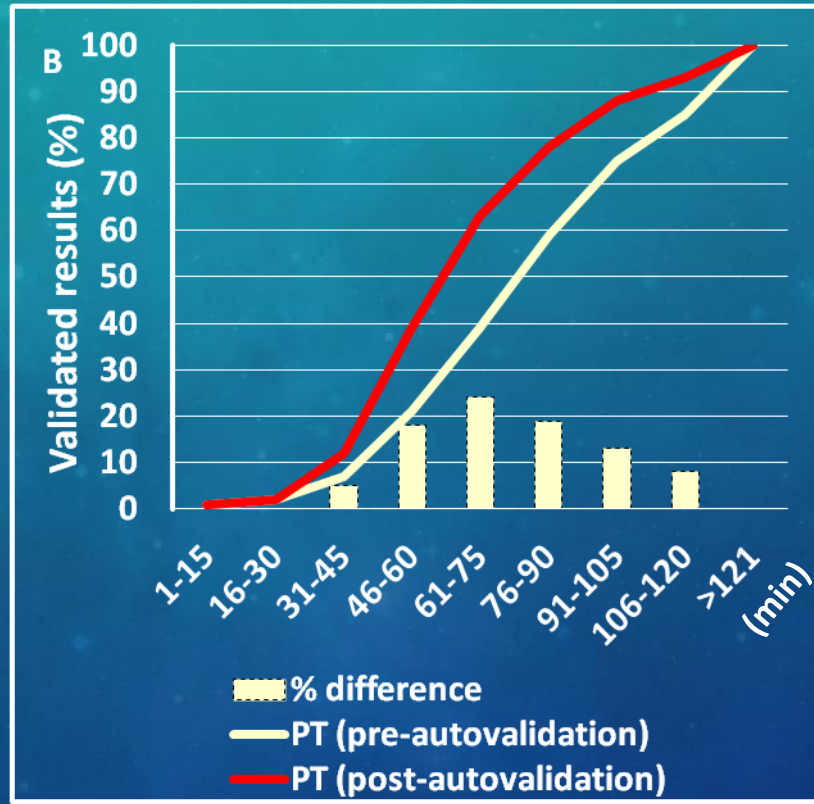
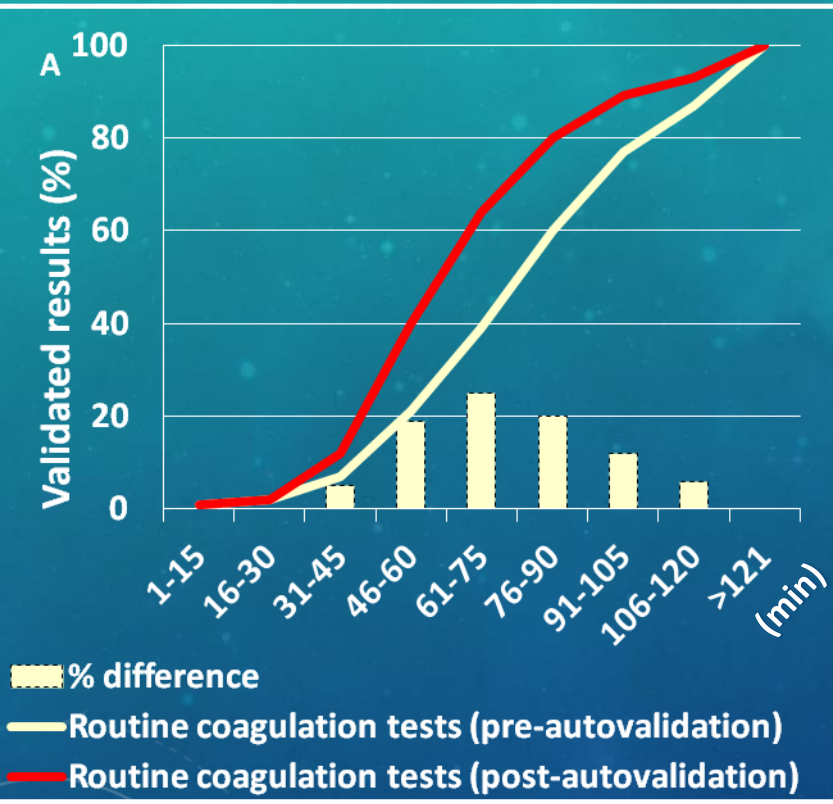
AUTO10-A
Vol. 26 No. 32
Replaces AUTO10-P
Vol. 26 No. 4

Autoverification of Clinical Laboratory Test Results;
Approved Guideline

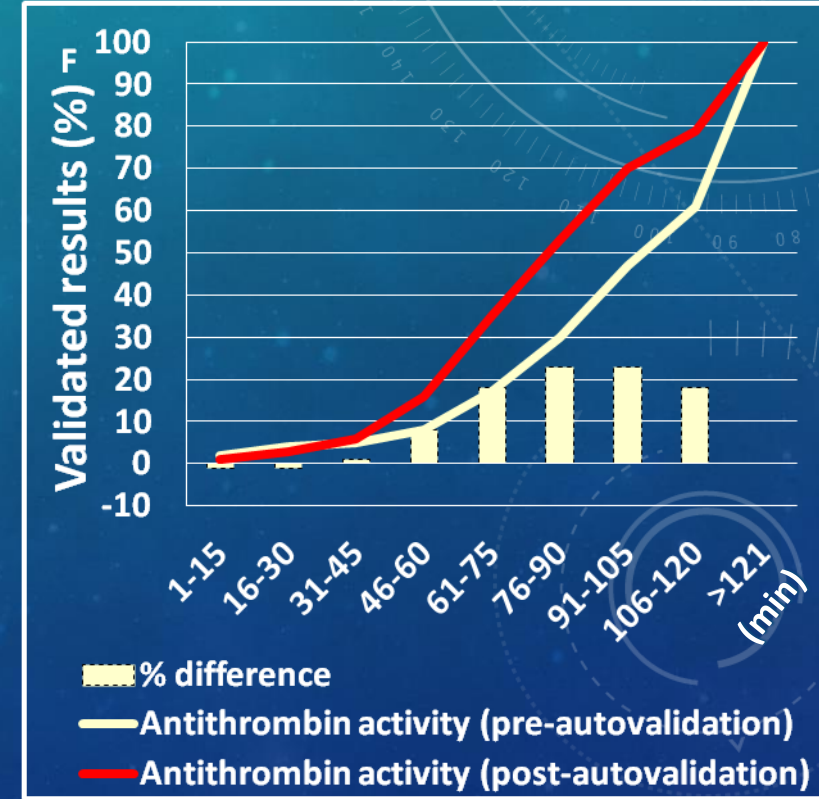
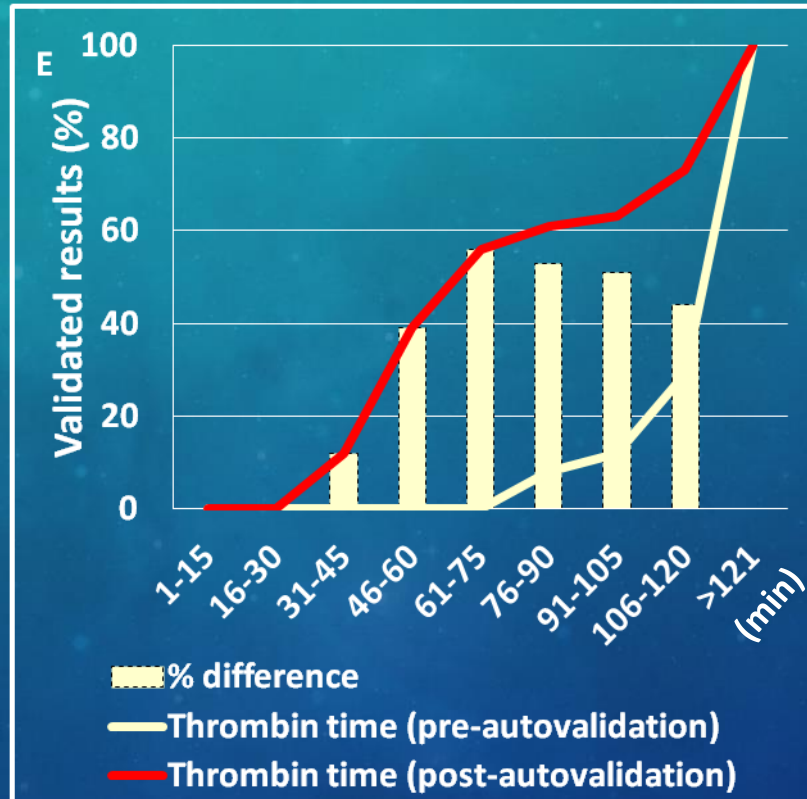
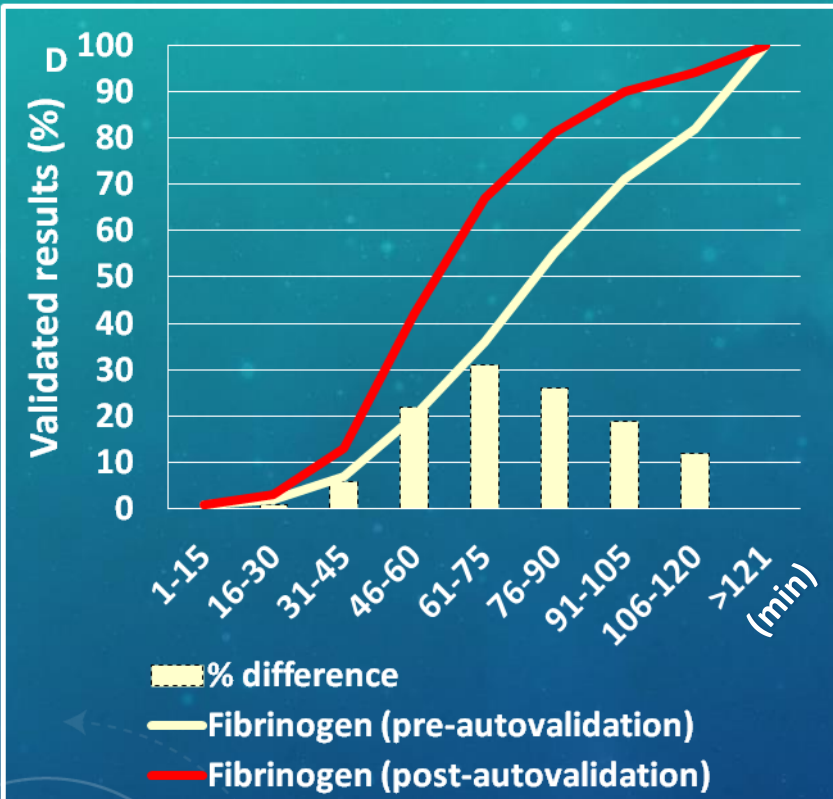
Verification of correctly defined specifications

Verification was performed by a laboratory specialist
on **2806** routine coagulation test requests
(completed when 2000 samples were analyzed continuously
without autoverification of an erroneous result)

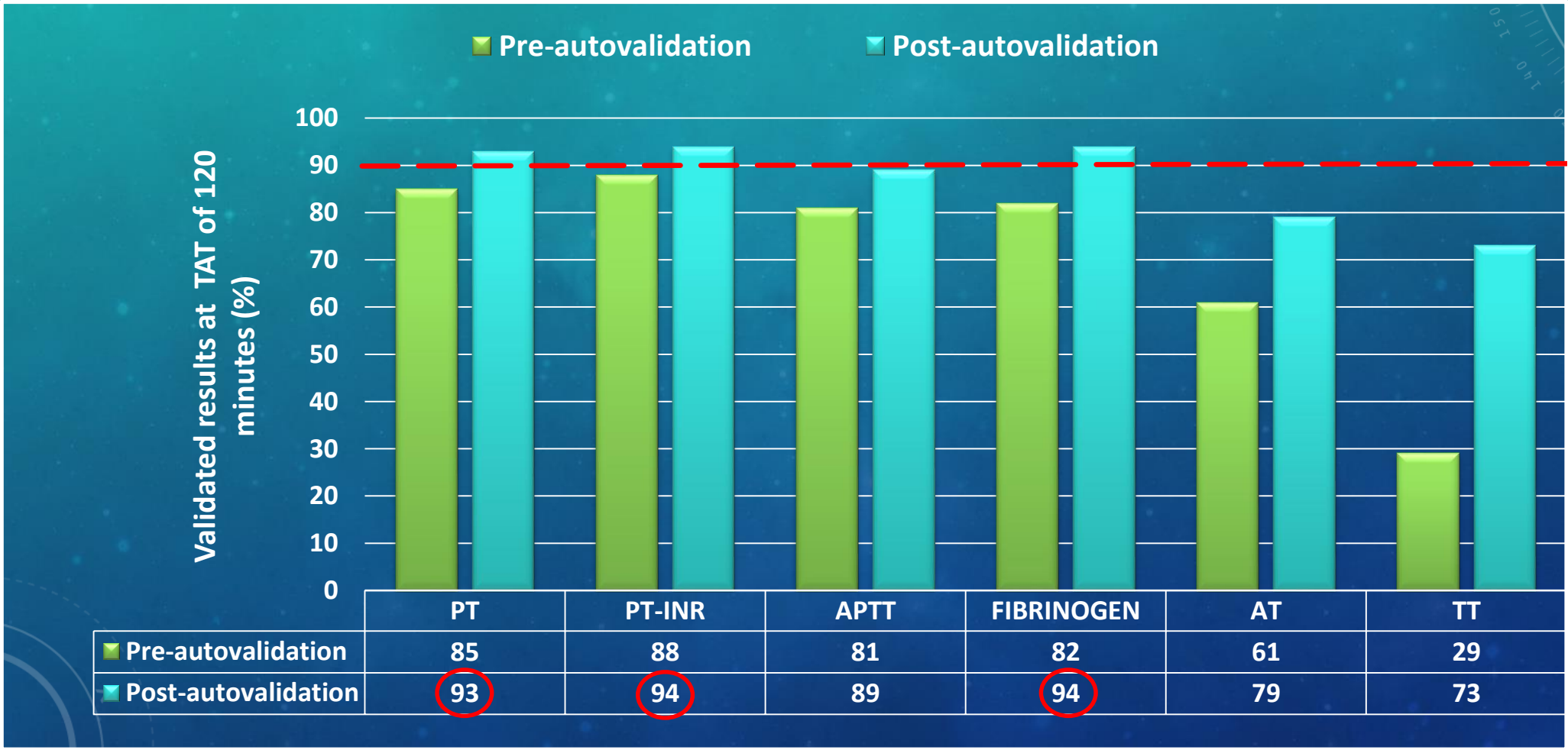
IMPROVEMENT OF TAT AFTER IMPLEMENTATION OF AUTOVALIDATION



IMPROVEMENT OF TAT AFTER IMPLEMENTATION OF AUTOVALIDATION



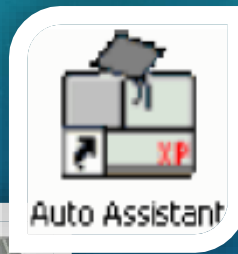
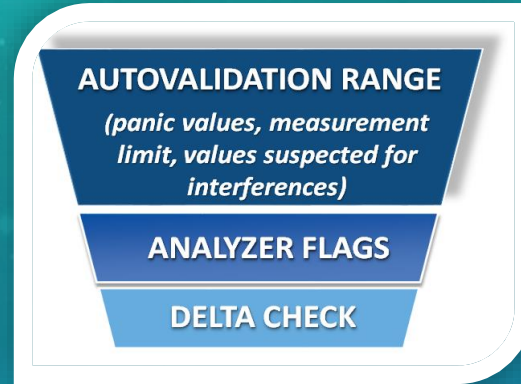
PERCENTAGE OF VALIDATED RESULTS AT TAT OF 120 MINUTES BEFORE AND AFTER IMPLEMENTATION OF AUTOVALIDATION



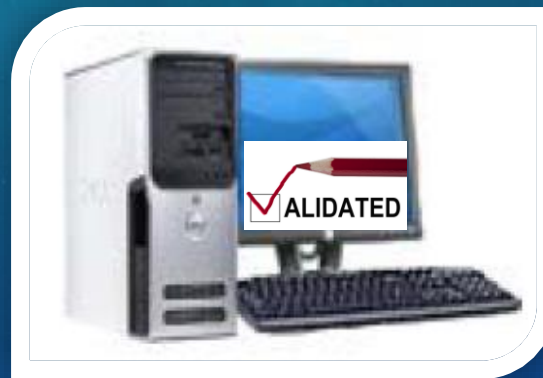
Goal TAT at 120 minutes (%)

AUTOVALIDATION ALGORITHM

AUTOVALIDATION



COAGULATION ANALYZER



MANUAL VALIDATION



CONCLUSIONS

All published studies proved that autovalidation of coagulation test results reduce the number of manually validated test results and decrease TAT for selected coagulation analysis, improving at the same time laboratory work efficacy.

The establishment of autoverification rules and parameters is still unclear, with no clear-cut autoverification rules which could be used, resulting in great variations of autovalidation rates depending on the setting and implemented autovalidation criteria.

Autovalidation can be relatively easily implemented in any coagulation laboratory by using “custom- made” autovalidation criteria tailored to the specific clinicians and laboratory needs.

ACKNOWLEDGEMENTS

Ana Mlinaric

Dunja Rogic

Vladimira Rimac

Renata Zadro

Marija Milos

Mirjana Fucek

Mr. Kresimir Kules for his valuable contribution to the autovalidation data extraction.

Thank you for attention!



