

# Poslijeanalitička faza u laboratorijskoj hematologiji

Branka Krešić

Zavod za medicinsko laboratorijsku dijagnostiku

KBC Split

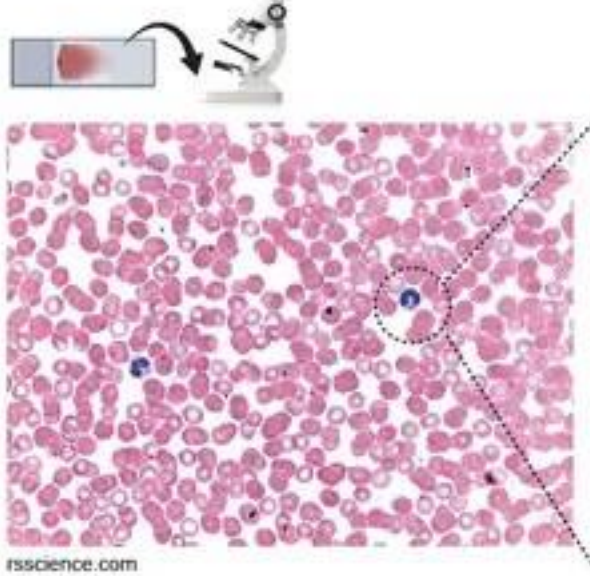
# Anketa RGLH HDMBLM

Table 7: Survey results related to results reporting.

Question	Answers	n (%)
39. How do you manage samples with results above hematology analyzer's measuring range?	a) Dilute the sample and report corrected result b) The initially obtained (native) result is reported from the hematology analyzer c) The result is reported as ">" of the upper limit of linearity of the respective analyser	91/129 (70) 15/129 (12) 23/129 (18)
40. How do you manage samples whose results are below hematology analyzer's measuring range?	a) The result is reported from the hematology analyzer b) The result is reported as "<" of the lower limit of linearity for certain parameters	37/129 (29) 92/129 (71)
41. Do you use autovalidation for hematology parameters?	a) Yes, for all parameters b) Yes, for certain parameters c) No	11/129 (9) 3/129 (2) 115/129 (89)
42. What is the monthly percentage rate of auto-validated results?	a) more than 50% b) Less than 50%	a) 5/9 b) 4/9
43. Which of the following criteria you use for autovalidation (multiple answers possible)	a) Delta check b) Combination of the following criteria: delta check, critical results, analysers flags, and/or linearity d) We do not use autovalidation	1/99 14/99 84/99
44. Please specify the applied TAT for STAT and routine CBC parameters.	Stat samples: a) Between 1 and 2 h b) Between 30 and 60 min c) Less than 30 min  Routine samples: a) 12-24 h b) 5-8 h c) 2-4 h d) Within 1 h	a) 10/118 (9) b) 90/118 (76) c) 18/118 (15)  a) 12/114 (10) b) 41/114 (36) c) 53/114 (47) d) 8/114 (7)
45. Which reference intervals do you use for reporting CBC results?, n=129	a) Recommended national harmonized reference intervals b) Recommendations from manufacturer c) Other (please specify)	129/129 (100) 0/129 0/129
46. Do you provide comments on your laboratory reports?, n=129	a) Yes, only predefined comments b) Yes, interpretative comments c) Yes, predefined and interpretative comments d) No, we do not report any comments	24/129 (19) 26/129 (20) 63/129 (49) 16/129 (12)
47. Do you report critical values for CBC?/do you communicate CBC critical values to referring clinicians?	a) Yes b) No	127/129 (98) 2/129 (2)
48. Do you have CBC critical values specified on laboratory report?	a) Yes b) No	11/129 (9) 118/129 (91)
49. Please specify the source of used critical values for CBC.	a) CCMB recommendations b) Thomas L., critical limits of laboratory results for Urgent clinician Notification c) CSMBLM national recommendations	a) 108/115 (94) b) 2/115 (2) c) 5/115 (4)

29% ???

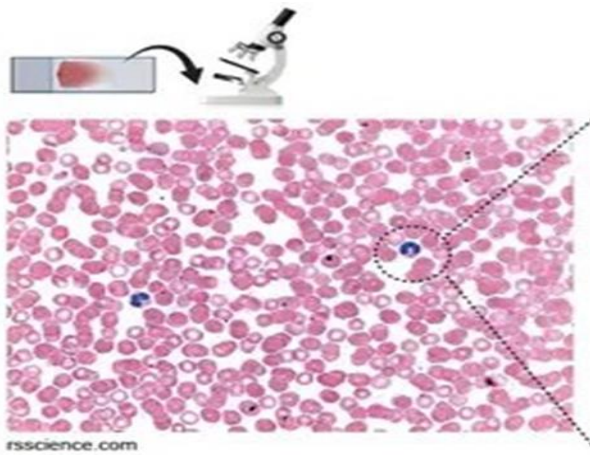
Nacionalne preporuke!



# Nalaz mikroskopskog pregleda

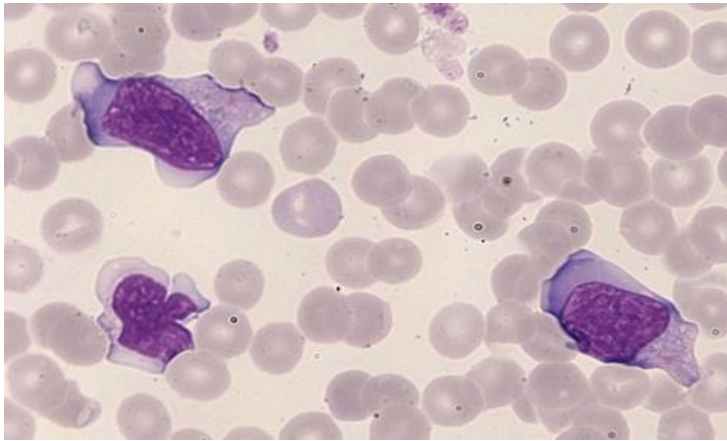
Interpretirati kliničku značajnost

Pružiti samo korisnu informaciju koja doprinosi diferencijalnoj dijagnozi



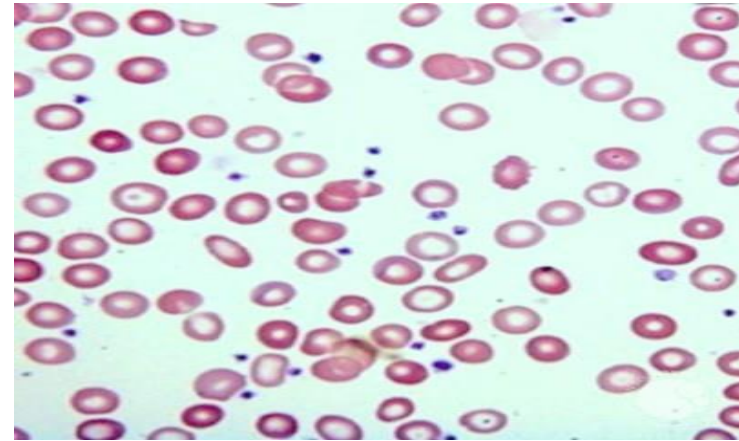
# Usporedivost rezultata

## Nomenklatura

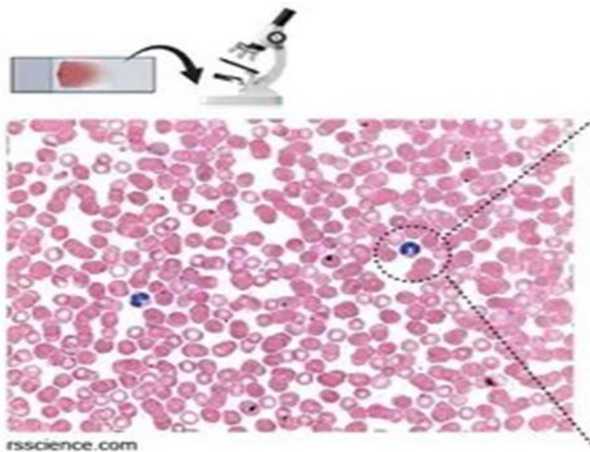


Reaktivni, atipični , varijabilni, aktivirani ...

## Stupnjevanje



Rijetki, + do ++++ (po vidnom polju ili %)...



# Usporedivost rezultata

International Journal of Laboratory Hematology

The Official Journal of the International Society for Laboratory Hematology

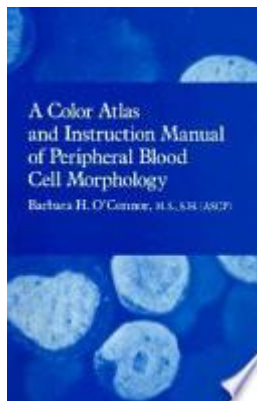


REVIEW

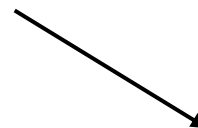
INTERNATIONAL JOURNAL OF LABORATORY HEMATOLOGY

## Reporting and grading of abnormal red blood cell morphology

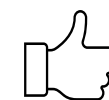
B. T. CONSTANTINO



Nema dokaza da je način  
superiorniji od drugih!



**Nacionalne smjernice**





## ICSH recommendations for the standardization of nomenclature and grading of peripheral blood cell morphological features

L. PALMER\*, C. BRIGGS<sup>†</sup>, S. MCFADDEN<sup>‡</sup>, G. ZINI<sup>§</sup>, J. BURTHEM<sup>¶</sup>, G. ROZENBERG<sup>\*\*</sup>,  
M. PROYTCHIEVA<sup>††</sup>, S. J. MACHIN<sup>†</sup>

2015.

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Standardizacija nomenklature i stupnjevanja morfoloških značajki



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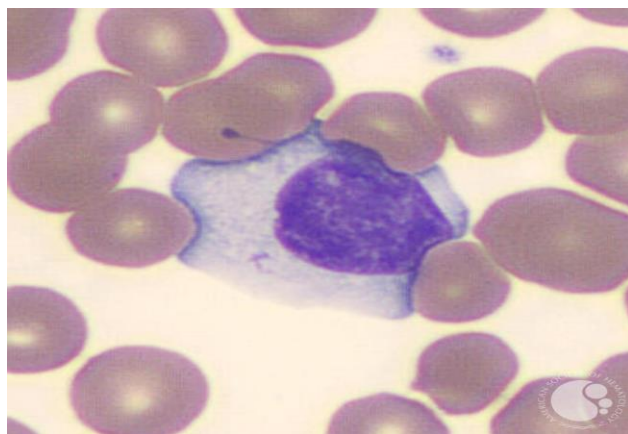
Pouzdana i ujednačeno izvještavanje rezultata



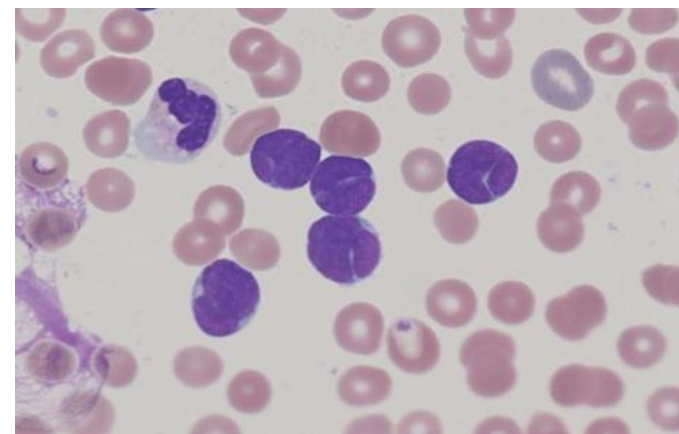


## ICSH recommendations for the standardization of nomenclature and grading of peripheral blood cell morphological features

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M. PROYTCHIEVA††, S. J. MACHIN†



**Reaktivni limfociti**  
Samo u značajnom broju kao  
odvojena populacija!



**Abnormalni engl. *abnormal*  
limfociti**



## ICSH recommendations for the standardization of nomenclature and grading of peripheral blood cell morphological features

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M. PROYTCHEVA††, S. J. MACHIN†

Table 1. Morphology Grading Table

% na najmanje 1000 eritrocita

RDW

MCV

Cell Name	Grading System		
	Few/1+	Mod/2+, %	Many/3+, %
RBC			
Anisocytosis	N/A	11–20	>20
Macrocytes	N/A	11–20	>20
Oval macrocytes	N/A	2–5	>5
Microcytes	N/A	11–20	>20
Hypochromic cells	N/A	11–20	>20
Polychromasia	N/A	5–20	>20
Acanthocytes	N/A	5–20	>20
Bite cells	N/A	1–2	>2



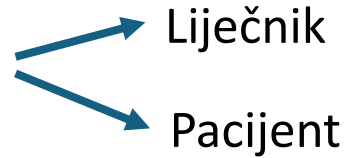
# Interpretativni komentari

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Klinička validacija nalaza

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Komunikacija laboratorij



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Dodatna vrijednost nalazu i kliničkoj primjeni različitih rezultata međusobno povezanih patofiziološkim procesom

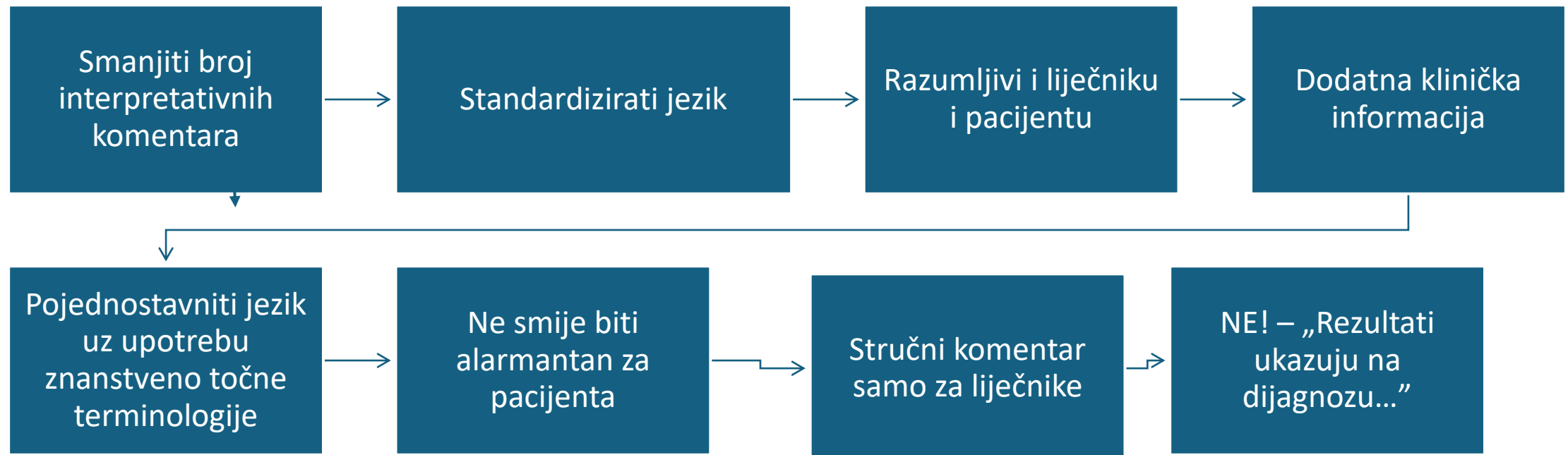


# SIBioC Diagnostic Hematology Study Group (DHSBG) 2014

Harmonizacija interpretativnih komentara u hematologiji

- 423 različitih interpretativnih komentara
- „Zbunjujuća slika” stanja u talijanskim laboratorijima
- Nedostatak standardizacije
- Različiti opisi iste morfološke promjene
- Dio ne izvještava o klinički značajnim promjenama

# SI BioC Diagnostic Hematology Study Group (DHSBG) 2014



**Table 1 WBC-Lymphocytes Group. Activated lymphocytes**

Code	Comment	Indication/action	references
1-LYMP	Presence of activated lymphocytes	To use for values of activated lymphocytes > 5%. For values <5%, the faculty to signaling the presence of activated lymphocytes depend on a careful evaluation of the context and the available data (clinical symptoms, serological and biochemical pictures)	7, 9-12
2-LYMP	Presence of activated lymphocytes and apoptotic cells	To use in co-presence of activated lymphocytes and lytic cells	
3-LYMP	The serological study is recommended	Add to 1-LYMP or 2-LYMP if serology has not already been requested	

➔ Nalaz

All three comments are extended to increase the clinical information for Physicians. This extended text is not in the laboratory report but in the appendix that was be sent “una tantum” to Physicians as a separate document that they can consult when specific comments are present in the hematologic report. For the IHCs from 1-LYMP to 3-LYMP the additional information is reported below:

Activated lymphocytes are the morphological equivalent of a functional state of the lymphocytes participating in the immunological response when a viral infection is present (from cytomegalic or *Epstein-Barr* and others). More rarely, non-viral agents can be involved such as *Toxoplasma gondii*; *Bordetella Pertussis* and others.

Because of the number of activated lymphocytes does not correlate with the prognosis and the evolution of the disease, the reporting of their presence only is enough in itself to direct towards the diagnostic hypothesis of infectious mononucleosis or mononucleosis-like syndromes.

Apoptotic lymphocytes represent the lithic terminal stage of the cell-virus interaction and constitute a confirmation, albeit indirect and not specific, of the reactive nature of lymphocytosis. Based on the patient's clinical picture, it may be useful to check for anti-EBV, anti-CMV (or others) IgM and IgG antibodies

➔ Liječnik

**Table 4. WBC - Lymphocytes group. The Adult Lymphocytosis**

Code	Comment	Indication/action	references
15-LYMP	The lymphocytosis must be confirmed in about three months	To use for lymphocytosis $>5.0 \times 10^9/L$ that have been observed for the first time and without the presence of atypical lymphocytes	16,26,27
16-LYMP	The lymphocytosis previously observed is confirmed. Cytofluorimetry is recommended	To use for lymphocytosis $>5.0 \times 10^9/L$ that have been observed for the first time at least three months before.	

the immunological response. The persistence/increase of the small lymphocytes could mean that they are clonal lymphocytes (non-reactive; neoplastic). This hypothesis requires a cytofluorimetric confirmation, since values of clonal lymphocytes  $>5.0 \times 10^9/L$  are WHO diagnostic criterium for chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). Values  $<5.0 \times 10^9/L$  characterize the Monoclonal B-Lymphocytosis (MBL).

A suggested operative algorithm in case of lymphocytosis:

- a. lymphocytosis  $>5.0 \times 10^9/L$  or LGL counting  $>2.0 \times 10^9/L$ : the CBC must be repeated after 3 and 6 months respectively
- b. the counting is confirmed: cytofluorimetry (CF) is required
- c. CF confirms the lymphocyte's clonality or LGL counting increases: you need to a haematological counselling

# Harmonisation of full blood count reports, recommendations of the French-speaking cellular haematology group (GFHC) 2015

Preporuke kod **inicijalne  
dijagnoze**

Konsenzus francuskih  
stručnjaka nakon validacije  
kliničkih hematologa

Na nalazu naznačiti da se radi  
o mikroskopskoj DKS (HR??)



# GFHC - interpretativni komentari

## Nisu automatski!

Razina 1 – jezgrovit **opis** morfologije

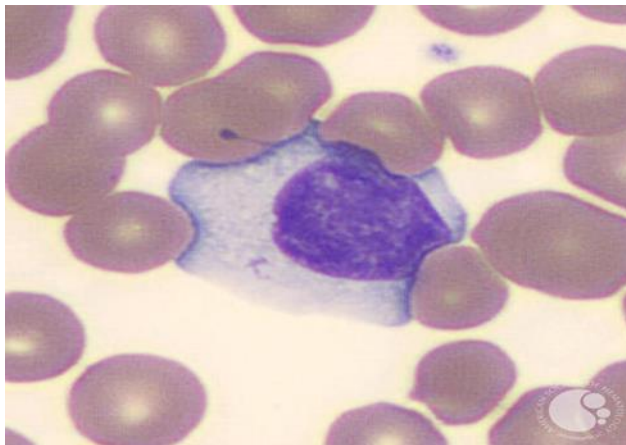
Razina 2 – **interpretacija** i ako je moguće usmjeravanje na dijagnozu

Razina 3 – **savjetovanje** o daljnjim testiranjima

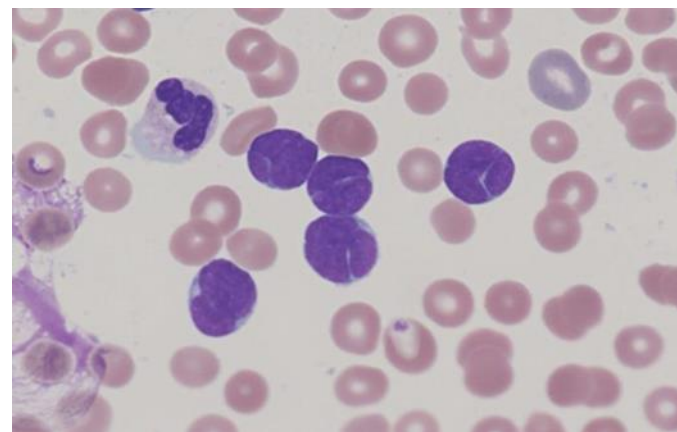
- Primatelj nalaza liječnik!
- Pacijent??



# GFHC



- Atipični reaktivni limfociti – „aktivirani“ funkcionalno obilježje
- Sve stanice se broje kao limfociti
- > 10% bazofilnih limfocita - samo komentar Razine 2 – „Sindrom mononukleoze“



- Sve stanice se broje kao limfociti
- Razina 1 – Jezgrovit opis stanica
- Razina 2 – Morfologija kompatibilna s ...
- Razina 3- Navesti dodatna testiranja

Dijagnoza!



# Nakupine trombocita

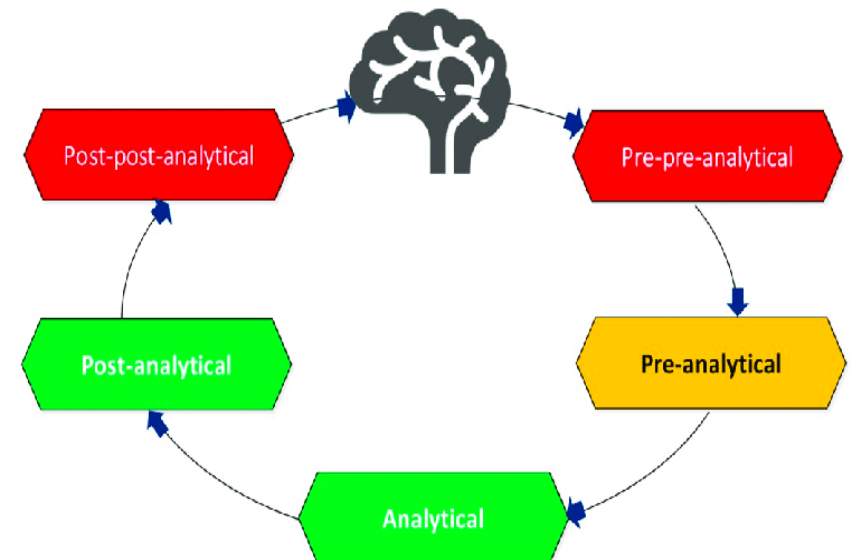
## SIBioc

5 - PLT	The platelets count was not performed due to the presence of agglutination. The numerical value of the platelets must not be given.	The instrumental numerical value of the platelets must not be given even if in the normal range.	54, 55
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Što je ispravno?

## GFHC

State 'Platelet count normal' if this is clearly so





**Best Practice when providing interpretative comments  
on laboratory medicine reports**

- Smjernice ne rješavaju glavno pitanje – za koji rezultat je potrebna klinička validacija
- Kompetencije (iskustvo) validatora
- Specijalnost liječnika koji prima nalaz
- Strah od zadiranja u kompetencije liječnika i odnos s pacijentom
- Klinički kontekst

**Dostupnost podataka o pacijentu!!!**

**Short communication**

**Interpretative comments - need for harmonization? Results of the Croatian survey by the Working Group for Post-analytics**

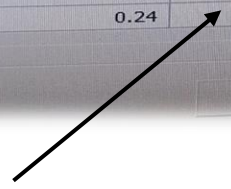
Vladimira Rimar<sup>1,2</sup> Sonja Podolar<sup>1,3</sup> Anja Inkir<sup>1,4</sup> Jelena Vlacir Tanackovic<sup>1,5,7</sup> Irena Honovic<sup>1,5</sup> Jasna Lenirek Krleža<sup>1,6,7</sup>



9. Which of the following do you think has the greatest impact on the quality of expert opinion in the case of laboratory professionals? (multiple-choice answers)	Limited access to patient's medical record	100 (62)
	Insufficient professional knowledge	15 (9)
	Lack of communication	19 (12)
	Unavailability/lack of interest of physician	104 (64)
	Lack of time	65 (40)

Smjernice kao edukativni materijal

	09.09.23 07:43:40 0901040407	07.09.23 07:13:43 0709010266	24.07.23 06:53:04 2407010201	23.05.23 06:44:50 2305050195	28.03.23 2803050195
1	1	1	1	1	1
7	6	6	6	6	6
	13.6 H	10.4 H			
	nema		10.8 H		
08	4.73	4.68	10.4 H	9.8 H	8.6
7	143	140	4.36	4.47	8.2
7	nema		127	132	4.31
170	0.453	0.439	143	125	132
2	95.8	93.8	0.431	0.386	129
9	30.2	29.9	90.5	88.6	0.390
5	316 L	319 L	30.2	29.2	0.406
5	nema		334	330	29.5
0	14.2	14.2	331	325	30.6
4	213	204	13.9	14.4	338
4	10.2	9.9	171	296	325
	nema		8.5	7.2	13.7
	nema				14.5
04	nema		51.7	48.5	193
	nema	0.001	0.002	0.001	187
	nema				7.5
	nema				52.1
	nema				57.7
	nema				0.001
	nema				
	nema				
	nema				
	nema				
	nema				
	nema				
	nema				
	27.8 L	31.4 L	34.3 L	40.5 L	38.8 L
	62.6 H	58.4 H	58.5 H	52.6 H	53.6 H
	6.6	7.2	4.7	5.0	4.7
	2.3	2.3	1.8	1.6	2.4
	0.7	0.7	0.6	0.4	0.3
	nema				
9	3.79	3.27	3.01	4.38	3.76
5	8.54 H	6.08 H	4.85 H	5.45 H	4.96 H
4	0.96 H	0.75	0.41	0.54	0.46
3	0.32	0.24	0.16	0.17	0.23



Prikaz rezultata

Pacijentica nakon liječenja karcinoma dojke

- Redovne kontrole
- 2 rezultata s brojem limfocita >5 x10<sup>9</sup>/L
- DKS mikroskopski

Podaci iz BIS-a:

- Nema nalaza hematologa
- Ne spominje se limfocitoza
- S onkološke strane sve u redu

**Svi uvjeti za interpretativni komentar!**



## HEMATOLOGIJA

Pretraga	Rezultat	Jedinica	Ref. interval	Opaska
<b>KRVNA SLIKA</b>				
(PK) Leukociti	7.9	x10 <sup>9</sup> /L	3.4 - 9.7	
(PK) Eritrociti	1.18 L	x10 <sup>12</sup> /L	4.34 - 5.72	
(PK) Hemoglobin	53 L	g/L	138 - 175	
(PK) Hematokrit	0.149 L	L/L	0.415 - 0.530	
(PK) MCV	126.3 H	fL	83.0 - 97.2	
(PK) MCH	44.9 H	pg	27.4 - 33.9	
(PK) MCHC	356 H	g/L	320 - 345	
(PK) Indeks rasp. Erc	21.1 H	%	9.0 - 15.0	
(PK) Trombociti	88 L	x10 <sup>9</sup> /L	158 - 424	
(PK) MPV	----	fL	6.8 - 10.4	
(PK) PDW	35.4	%	35-65	
(PK) PCT	0.001	L/L	0.001 - 0.004	
(PK) Makrocitoza	+++			
(PK) Anizocitoza	+++			
<b>DIFERENCIJALNA KRVNA SLIKA</b>				
(PK) Promijelociti	1.0 H	%	0	
(PK) Neutrofili granulociti	55.0	%	44 - 72	
(PK) Atipični limfociti	2.0 H	%	0	
(PK) Limfociti	39.0	%	20 - 46	R.I. za odraslu dob
(PK) Monociti	3.0	%	2 - 12	
DKS mikroskopski	/			
(PK) Eritroblasti	1 H	/100 Lkc	0	
(PK) Retikulociti	14.2	/1000 Erc	5 - 21.6	
(PK) Retikulociti#	16.80 L	x10 <sup>9</sup> /L	22 - 97	
(PK) Napomena	Neutrofili granulociti hipersegmentirane forme.anizopokilocitoza ++.U razmazu periferne krvi vidjeni megaloociti.			

Izradio/a:

Validirao/a:

## KOAGULACIJA

Pretraga	Rezultat	Jedinica	Ref. interval	Opaska
(P) PV	0.86		> 0.70	
(P) APTV	23.8	s	23.2 - 30.4	

(P) APTV-omjer	0.85		0.8 - 1.2	
(P) Fibrinogen	1.3 L	g/L	1.8 - 3.5	
(P) D-Dimeri	1.51 H	mg/L	< 0.50	

Izradio/a:

Validirao/a:

## BIOKEMIJA

Pretraga	Rezultat	Jedinica	Ref. interval	Opaska
<b>METABOLITI I SUPSTRATI</b>				
(S) Glukoza	6.3	mmol/L	4.4 - 6.4	
(S) Ureja	7.0	mmol/L	2.8 - 8.3	
(S) Kreatinin	70	µmol/L	64 - 104	Jaffe (kompenzirana metoda)
Procjena glomerularne filtracije (eGFR) - CKD-EPI	97.5	mL/min/1.73m <sup>2</sup>	Kategorija GFR (KDIGO 2012.): G1: >90 G2: 60-89 G3a: 45-59 G3b: 30-44 G4: 15-29 G5 < 15	Primjenjuje se uz poznata ograničenja!
(S) Urati	198	µmol/L	182 - 403	
(S) Ukupni bilirubin	19	µmol/L	3 - 20	
(S) Konjugirani bilirubin	7 H	µmol/L	< 5	
(S) Nekonjugirani bilirubin	12	µmol/L		
<b>ENZIMI</b>				
(S) Aspartat-aminotransferaza (AST)	98 H	U/L	11 - 38	
(S) Alanin-aminotransferaza (ALT)	65 H	U/L	12 - 48	
(S) Gama-glutamitranferaza (GGT)	15	U/L	11 - 55	
(S) Laktat dehidrogenaza (LDH)	3967 H	U/L	103 - 241	
(S) Alkaha fosfataza (ALP)	52 L	U/L	60 - 142	
<b>PROTEINI</b>				
(S) Ukupni proteini	67	g/L	66 - 81	
(S) Albumin	45.2	g/L	40.6 - 51.4	
(S) C-reaktivni protein	< 0.6	mg/L	< 5.0	
(S) NT-proBNP	125	pg/mL	<386	Roche ECLIA
(S) hs-Troponin T	8.5	ng/L	< 14 ng/L	Roche ECLIA
<b>ELEKTROLITI</b>				

## GFHC

Razina 1 Hipersegmentirani neutrofili + makrocitoza

Razina 2 Rezultati ukazuju na megaloblastičnu deficijentnu dismijelopoezu

Razina 3 Odrediti vitamine

Laboratorij: refleksno retikulociti, mikroskopski pregled

Bez interpretativnog komentara

Dežurni liječnik nakon nalaza:

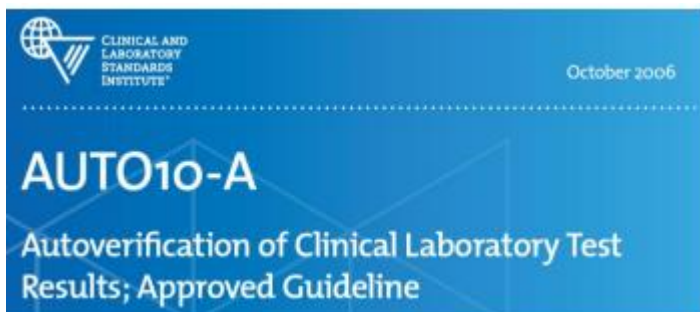
Jako je visok LDH, akutna hemoliza? B12, folna kiselina?



# Autovalidacija

- Automatsko izdavanje nalaza bez ručne intervencije
- Ujednačen proces procjene svakog nalaza
- Svaki rezultat prolazi jednaka pravila – kvaliteta rezultata.

# Kako započeti?



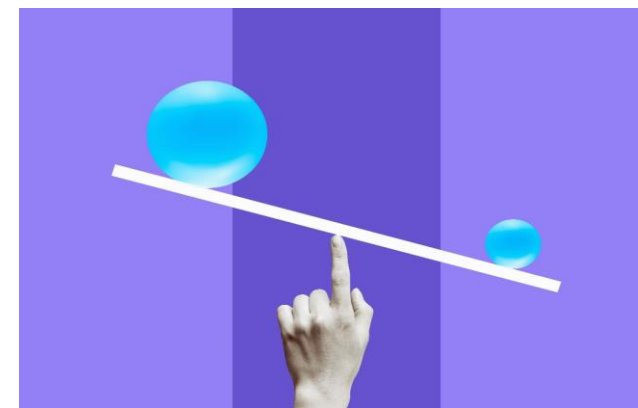
## Technical Note

### Use of Middleware Data to Dissect and Optimize Hematology Autoverification

Rachel D. Starks<sup>1</sup>, Anna E. Merrill<sup>1</sup>, Scott R. Davis<sup>1</sup>, Dena R. Voss<sup>1</sup>, Pamela J. Goldsmith<sup>1</sup>, Bonnie S. Brown<sup>1</sup>, Jeff Kulhavy<sup>1</sup>, Matthew D. Krasowski<sup>1</sup>

<sup>1</sup>Department of Pathology, University of Iowa Hospitals and Clinics, Iowa City, IA, USA

Želje i mogućnosti

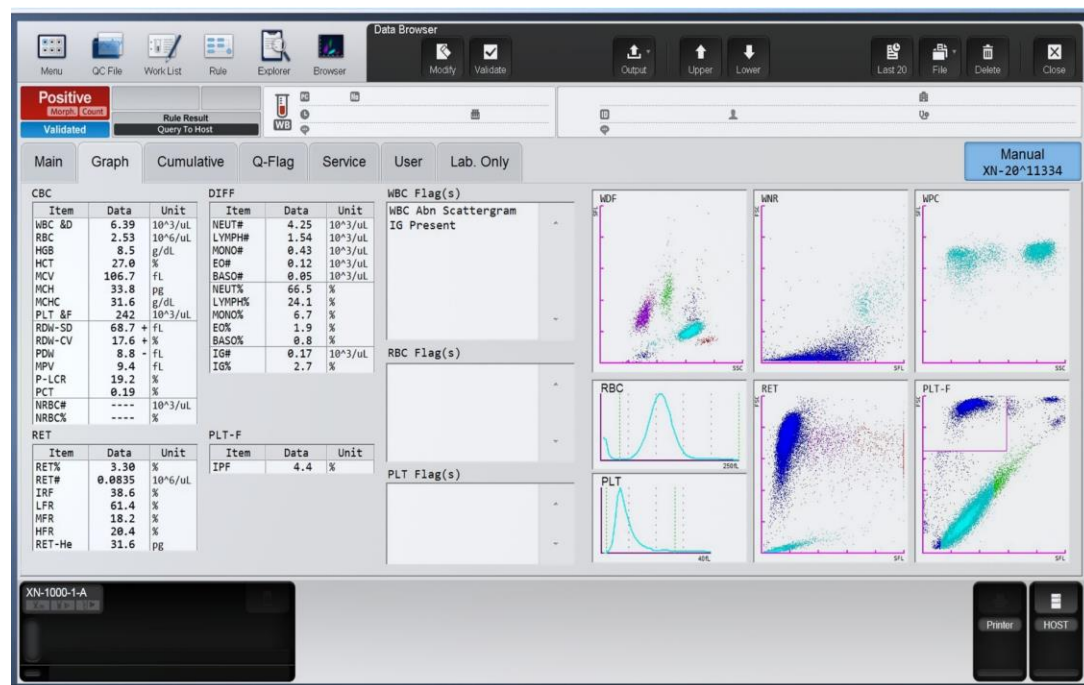


# Autovalidacija u hematologiji

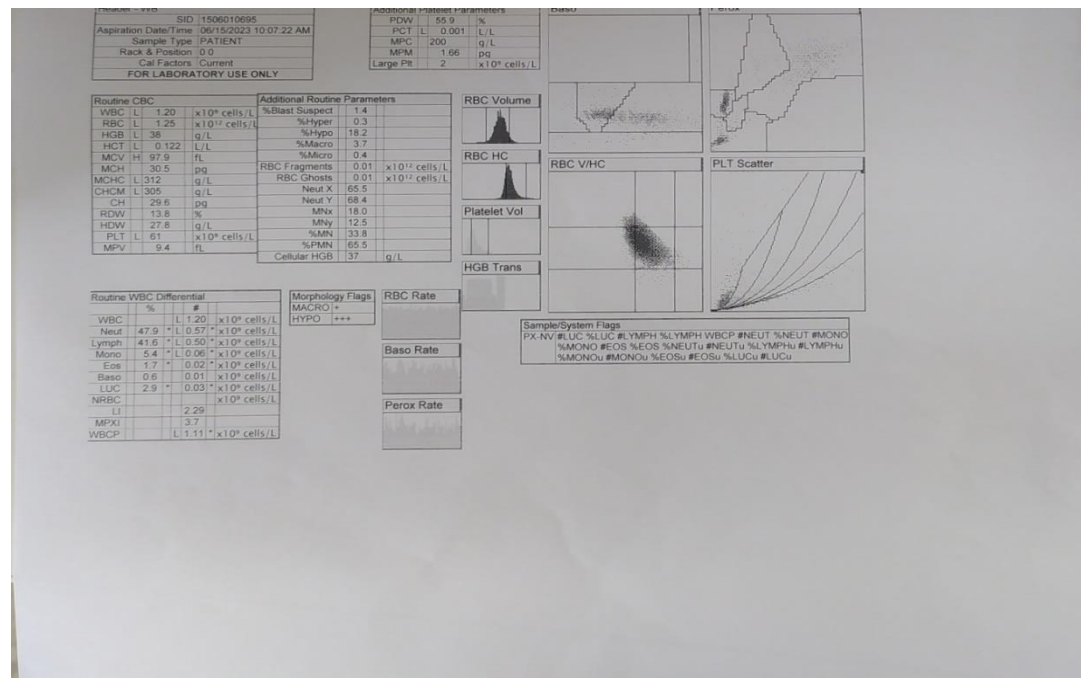
- Nema pregleda rezultata i verifikacije – procjena u programskom sustavu
- Osigurati adekvatnu komunikaciju s programskim sustavom – LIS i/ili međusustav engl. *middleware*
- Definirati što je rezultat ("----" ili „\*\*\*\*“, broj, „nema“ )
- Postavke analizatora za zaustavljanje i automatsko slanje rezultata

# Procjena rezultata u hematološkom laboratoriju

## Pregled i validacija na analizatoru



## Pregled detaljnog ispisa



# Kriteriji - delta check

CLSI AUTO15 2.3.21 osnovni uvjeti

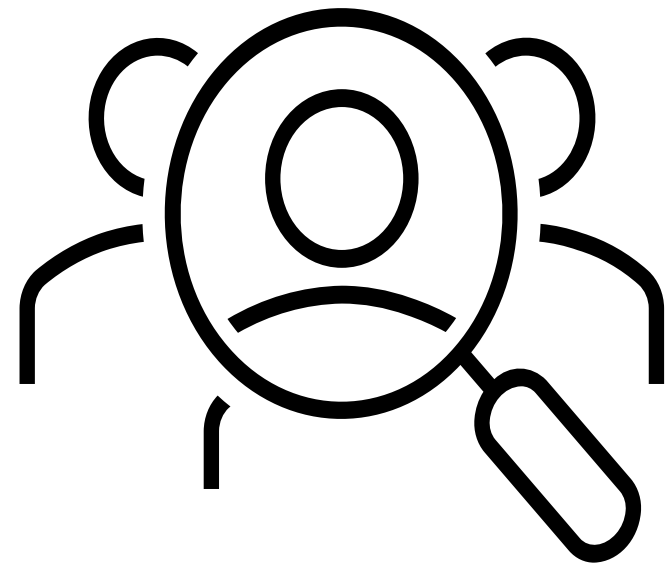
- Prethodni rezultat
- Što ako ga nema ( „/” umjesto rezultata) ili je rezultat „<”
- Rezultati koji nisu izdani ili su naknadno povučeni moraju biti uklonjeni iz programskog sustava

# DELTA check-cilj

- [CLSI EP33 ED2:2023 — Use of Delta Checks in the Medical Laboratory, 2nd Edition](#)
- Detekcija pogrešne identifikacije pacijenta
- Detekcija problema s uzorkom (nakupine, razrjeđenje uzorka)
- Klinički značajna promjena kod pacijenta
  
- Analitički problemi – učestala kalibracija
- Pogreške kod ručnog unosa rezultata?

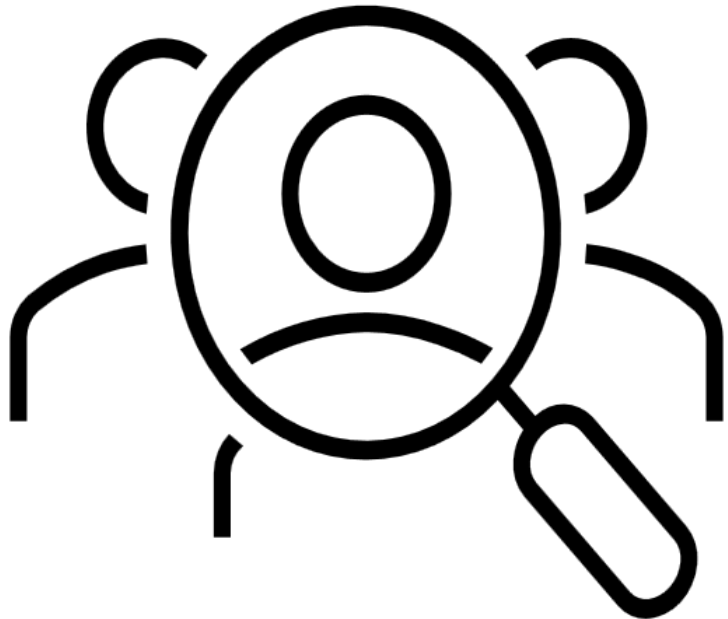


Populacija pacijenata +



Neočekivana promjena





## Pretrage

- MCV
- Hemoglobin
- Leukociti
- Trombociti
- Neutrofilni granulociti

# DELTA check

- Za detekciju pogrešne identifikacije pacijenta parametri koji su stabilni u određenom vremenskom razdoblju – MCV
- Mali broj akutnih stanja uzrokuje promjenu

PRETRAGE IZVAN "DELTA" VRIJEDNOSTI

PRETRAGE IZVAN "DELTA" VRIJEDNOSTI.

Pretraga	Rezultat	DELTA CHECK		
		Postotak	Validirano	Rezultat
▶ 01. Hematologija (PK) MCV	88.6	5,00 %	20.11.2024	83.6
04. Biokemija (S) <b>Natrij</b>	140	5,00 %	20.11.2024	133
04. Biokemija (S) Kalij	4.5	25,00 %	20.11.2024	3.0
04. Biokemija (S) Kloridi	104	10,00 %	20.11.2024	94

# Način izračuna

- Apsolutna razlika
- Relativna razlika %
- Relativna razlika / vremensko razdoblje
- Relativna razlika / raspon RI

# Granice prihvaćanja - delta check limits

- Empirijske literatura ili temeljene na iskustvu
- RCV
- Klinički značajna razlika - korist u bolničkoj populaciji?

**KBC Split RCV za hemoglobin 6%**

# Literatura

## $\Delta$ MCV

- 3- 6 fL
- 3- 10%
  
- $\Delta$  Hgb 15- 35%
- $\Delta$  Trc 35-50%
  
- Ovisno o cilju:  $\Delta$ A detekcija značajne promjena rezultata (MCV 5%)  
 $\Delta$ B detekcija pogreške (MCV 10%)

# Development and Evaluation of a Logical Delta Check for Identifying Erroneous Blood Count Results in a Tertiary Care Hospital

Ira Miller, MD, PhD

- $\Delta$ MCV - 3fl
- 3 dana
- Niska specifičnost i osjetljivost za detekciju pogreške
- „composite CBC delta (CCD) check”

$$\text{CCD} = \sqrt{([50 \times \Delta\text{Hb}]^2 + [100 \times \Delta\text{MCH}]^2 + [100 \times \Delta\text{RDW}]^2 + [1.5 \times \Delta\text{PLT}]^2)}$$

$$\text{HMR} = \sqrt{([50 \times \Delta\text{Hb}]^2 + [100 \times \Delta\text{MCH}]^2 + [100 \times \Delta\text{RDW}]^2)}$$

- logical delta check (LDC) - CCD >250 and HMR >116

# Development and Evaluation of a Logical Delta Check for Identifying Erroneous Blood Count Results in a Tertiary Care Hospital

Ira Miller, MD, PhD

**Table 2.**

Characteristics of Failures for CCD and LDC Using Cutoff Values Indicated in the Text

Variable	CCD	LDC
Length of evaluation period, d	14	35
Total CBCs performed during the evaluation period, No.	11 193	26 566
Total delta checks, No. (% of CBCs with recent priors)	5792 (52)	13 234 (50)
Failed delta checks	<b>(n = 110)</b>	<b>(n = 205)</b>
Interim transfusion, No. (%)	54 (49)	76 (37)
No interim transfusion, valid based on medical record review, No. (%)	39 (36)	85 (42)
Failure due to platelet change only, No. (%)	14 (13)	0
Presumed or confirmed mislabeled, No. (%)	9 (8), comprising 5 events	16 (8), comprising 15 events
Failure due to other problem, No. (%)	<b>8 (7)</b>	<b>28 (14)</b>
Specimen dilution from intravenous fluid in line, No.	3	11
Analytic (agglutinin or unmixed specimen), No.	5	17
Failed tests		
Both MCV delta (>3.0 fL) and CCD, No.	38 <sup>a</sup>	Not determined
Both MCV delta (>3.0 fL) and CCD, presumed or confirmed mislabeled, No./total No.	2/38, comprising 1 event	8/13 assessable LDC failures

Abbreviations: CBC, complete blood cell count; CCD, composite CBC delta; LDC, logical delta check; MCV, mean red blood cell volume.

<sup>a</sup> There were 269 MCV delta check failures (5% of values with recent priors) in this period.

# Programski sustavi

## Idealno

- Različita pravilo za niske, normalne i visoke vrijednosti
- Različiti kriteriji ovisno o smjeru promjene
- Lokacija pacijenta

## Realno

- Jedno pravilo za sve



# Jedno pravilo za sve

- Kriterij za trombocite **40%**

*trenutni rezultat – prethodni rezultat / prethodni rezultat × 100*

Trc trenutni	280 x 10 <sup>9</sup> /L
Trc prethodni	178 x 10 <sup>9</sup> /L
Δ	57%

▽ 21%

Trc trenutni	88 x 10 <sup>9</sup> /L
Trc prethodni	195 x 10 <sup>9</sup> /L
Δ	55%

# Uzroci promjena rezultata hematoloških parametara

- Promjene kliničkog stanja pacijenta (krvarenje, sepsa...)
- Terapijski postupci (transfuzija, infuzija, operacija, primjena antibiotika, kemoterapija, heparin...)
  
- Razrjeđenje uzorka
- Pogreške u identifikaciji
- Analitički problemi

# Verifikacija $\Delta$ check kriterija

Glavni cilj detekcija **neočekivanih razlika** u rezultatima

- Posljedica pogreške (Hgb razrjeđenje)
- Stvarna promjena koja zahtjeva neodgodivu komunikaciju s liječnikom (Hgb akutno krvarenje)
- Lažno negativni (autovalidirani nalazi kojima  $\Delta$  check nije detektirao neočekivanu promjenu)
- Lažno pozitivni (nalaz nije autovalidiran, a detektirana promjena je očekivana)

**Prilagoditi dozvoljena odstupanja**



Minimalan broj lažno pozitivnih uz prihvatljivu stopu detekcije neočekivanih rezultata

# Autovalidacijski raspon

**Određuje se za svaki parametar prema vlastitoj populaciji pacijenata**

- Referentni interval
- AMR
- Kritične vrijednosti
- Vrijednosti koje nisu moguće
- Kriterij za mikroskopski pregled
- Vlastiti kriteriji
- Interferencije

**Rezultati koje želimo zaustaviti kada nema upozorenja s analizatora i prethodnog rezultata**

# Primjer 1 - Hemoglobin

## Literatura AV raspon – kritične vrijednosti

Hgb 171 g/L+ HDP + 5 g. =



Autovalidacija



## AV raspon 66-199 g/L

Slijedeći dan Hgb 141 g/L

Delta check zaustavlja autovalidaciju

Pregled arhive: djeca do 10 godina rijetko  
vrijednosti iznad RI (max 15g/)

**Prilagođen AV raspon!**

# Primjer 2 -Eozinofilni granulociti

**AV raspon 0 - 25% - na temelju verifikacije i iskustva**

**Danas veliki broj pacijenata s  
povišenim % eozinofila**



**Dnevna usporedba uređaja** ✓

**Autovalidacija** ✓

Rezultati na drugom analizatoru unutar RI

Uzrok: problem s analizatorom rezultati bez  
„flaga”

Nije promijenjen AV raspon!



## Customized middleware experience in a tertiary care hospital hematology laboratory

Kristine Roland <sup>\*</sup>, Jim Yakimec, Todd Markin, Geoffrey Chan, Monika Hudoba

*Vancouver General Hospital, Vancouver, BC, Canada*

K. Roland et al.

Vrijeme uzorkovanja

Journal of Pathology Informatics 13 (2022) 100143

**Table 1**  
Middleware rules for complete blood count, differential and coagulation testing.

Rule source	Rule	Hold for review	Notes
<i>CBC and differential</i>			
DI	Sample collection time >24 h	CBC, Diff	Suppress Auto diff + RBC indices
DI	Sample collection time >72 h	Reticulocyte	Not reported
DI	Patient age <3 days		Reflex CBC, Diff, NRBC, Retic, Smear
DI	★ WBC <0.5	Diff	Reflex smear review + referral
DI	WBC <0.5 + previous WBC >1.0 + not oncology		Reflex smear review + referral
DI	WBC >30.0 + Outpatient		Reflex Diff
DI	WBC 250.0 – 450.0	Diff	Report RBC indices as Unavailable
DI	WBC exceeds linearity	WBC, HCT, Diff, Reticulocyte	Report RBC indices as Unavailable
DI	WBC lower limit of quantitation		Report WBC as < x.x
DI	★ Neutrophil # <1.0 + not oncology		Reflex smear review
DI	★ Neutrophil # <0.5		Follow Critical Result SOP + referral
DI	★ Neutrophil # >30.0		Reflex smear review
DI	Neutrophil # >50.0		Referral if no previous >50.0
DI	Lymphocyte # > reference interval Child		Reflex smear review + referral
DI	★ Lymphocyte # >5.5 Adult		Reflex smear review + referral
DI	★ Monocyte # >2.0 + Neutrophil # <8.0		Reflex smear review
DI	★ Monocyte # >3.0		Reflex smear review + referral
DI	Eosinophil % >20.0	Diff	Reflex smear review
DI	★ Eosinophil # >2.0		Reflex smear review + referral
DI	★ Basophil # >0.5	Diff	Reflex smear review + referral
DI	★ IG % >5, or >10 + previous <5, or >20 + previous <10		Reflex smear review
DI	★ NRBC % >2.0 + not ICU/oncology		Suppress IG # <0.2
DI	NRBC % >25.0 + patient age <31 d		Reflex smear review + referral
DI	NRBC linearity	WBC, Diff, NRBC	Reflex smear review + referral
Systemx/DI	WBC abnormal scattergram + WBC >0.5	Diff	Reflex smear review
Systemx/DI	Abnormal lymphocytes/blasts flag	Diff	Reflex smear review

Odjel

★ denotes if no previous test result



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DI		Turbidity/Hb interference + MCHC >375	All results	17 days: <u>1</u> to Adult, <u>1</u> to Child
Systemx/DI			CBC, Diff	Reflex rerun, Dilute X7
DI		HCT >0.55, add Patient User Field		For use in coagulation rules
DI		HCT linearity	CBC	Dilute X7
DI	★	MCV outside reference interval – Child		Reflex smear review + referral
DI		MCV delta failure	All results	60 days: + 5 Adult, + 4 Child
Systemx/DI		MCV <60	PLT	Reflex PLT-F
DI		MCV <80 + RBC, HB, RDW, Age, Gender		<u>Auto comments - Microcytosis</u>
DI	★	MCV <80 + HB <50 or HB >165 male or >150 female		Reflex smear review and referral
DI	★	MCV 105-110 + HB <100 or PLT <50 or Neutrophil# <1.0		Reflex smear review and referral
DI	★	MCV >110		Reflex smear review
Systemx/DI		MCHC <275 or > 375	All results	Referral with exceptions
DI	★	PLT <100		Reflex rerun
DI		PLT <75 + previous >120	All results	Reflex smear review
DI	★	PLT <50	All results	Child – critical result



# % autovalidiranih nalaza

- Postavljenim pravilima
- Specifikacijama hematološkog analizatora
- Mogućnostima automatizacije dodatnih postupaka
- Dostupnosti međusustava
- Mogućnostima LIS-a



Unatoč ograničenjima uz osnovne kriterije broj autovalidiranih nalaza > 50%



Hvala na pažnji!