

Laboratory aspects of acute diseases surveillance and the needs for QA/QC

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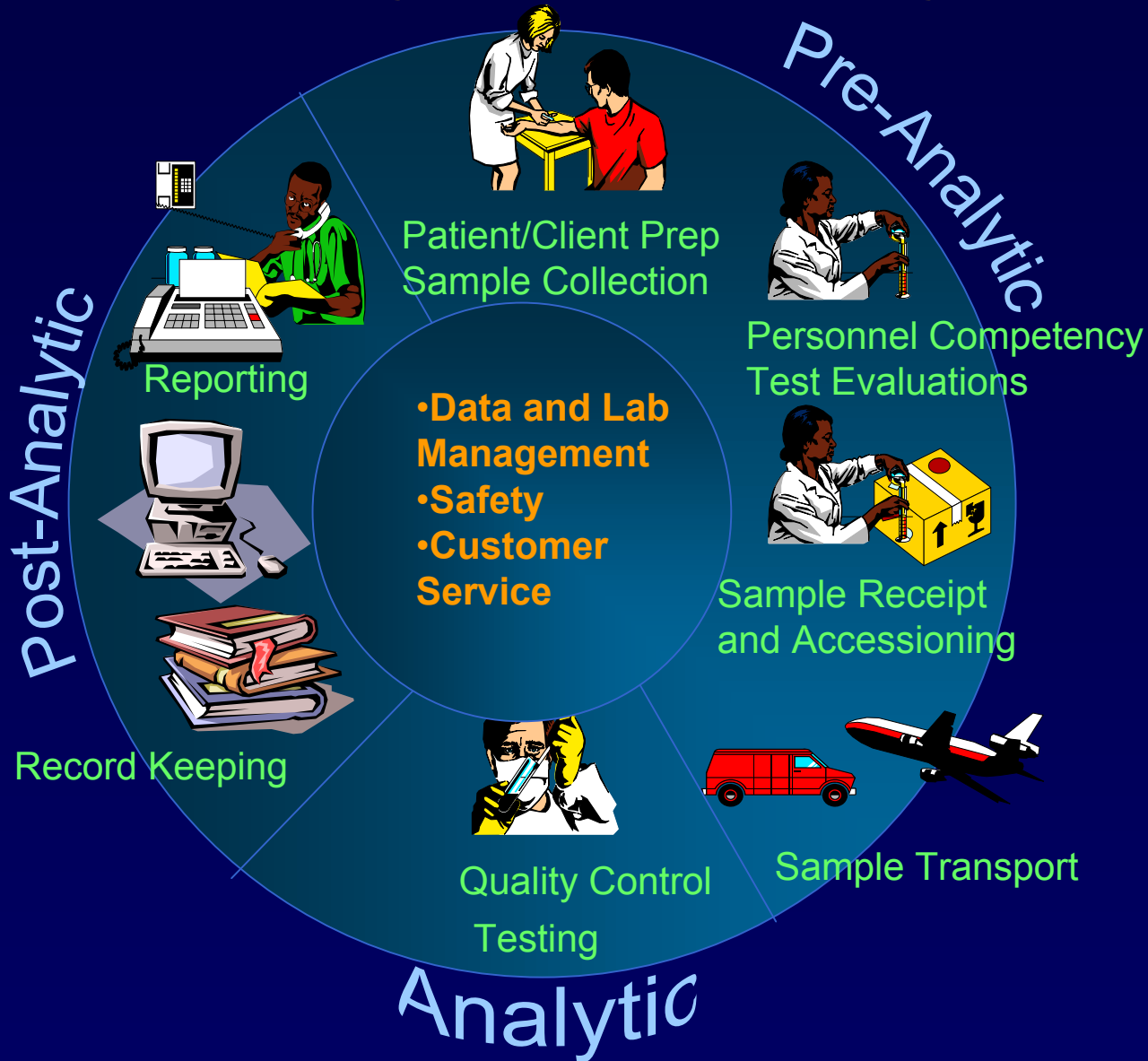
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The Quality Assurance Cycle



Features of laboratory service in Central Asia region

- Absence of continuously postgraduate education for laboratory specialists
- Short supply with technical facilities
- Absence of laboratory control of test kits
- Absence of steady monitoring for analysis quality in every single laboratory (IQCI) and state (EQC)

GOAL

- **Establishing and implementation of laboratorial quality assurance system for HIV and viral hepatitis diagnosing in states of Central Asia**

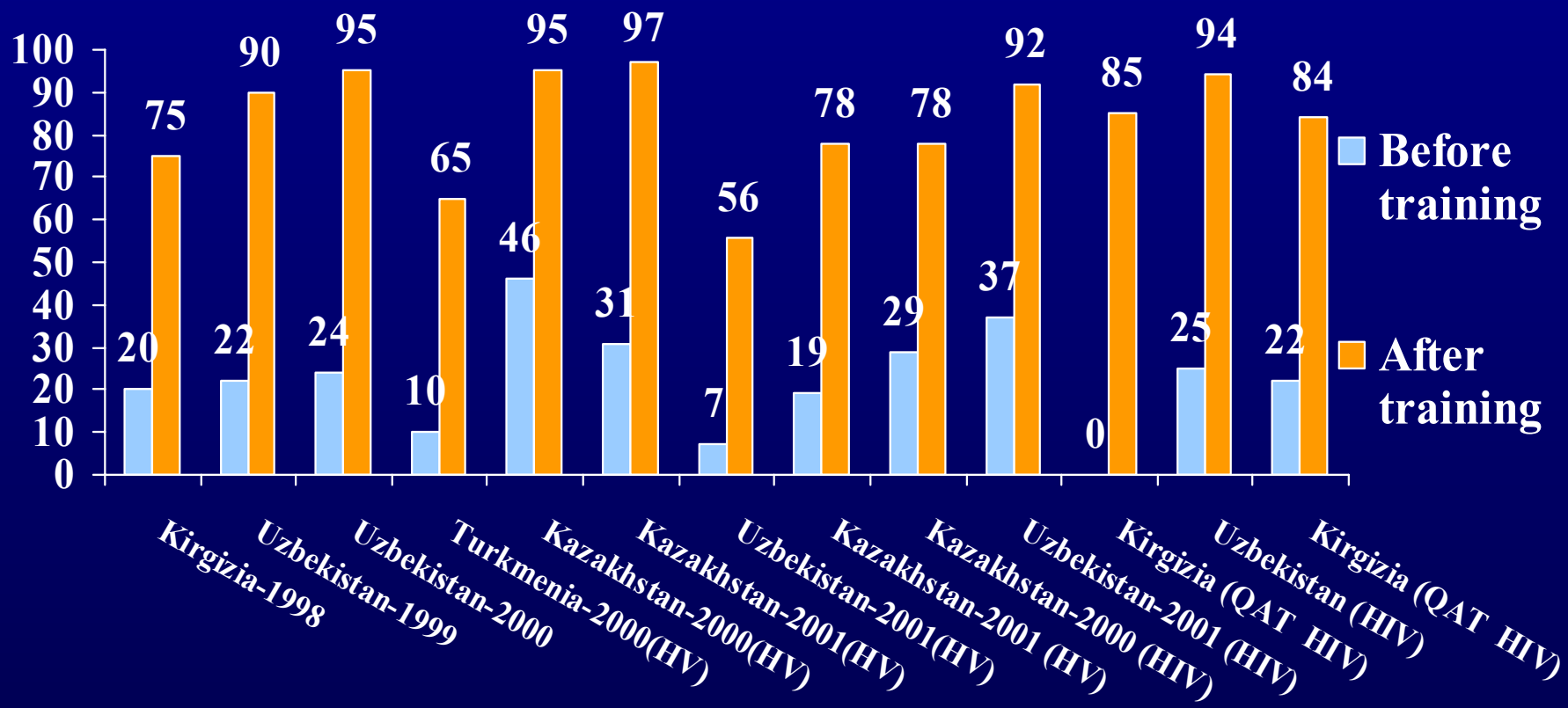
OBJECTIVES

- **Training** of Central Asia specialist of rules of quality assurance and quality control (QA/QC)
- **Establishing** national reference-laboratories (NRL) for implementation of basis of QA – **Internal Quality Control and program of External Quality Control**
- 3. Creation of background for **further development of QA** through integration of NRL to present laboratory service system

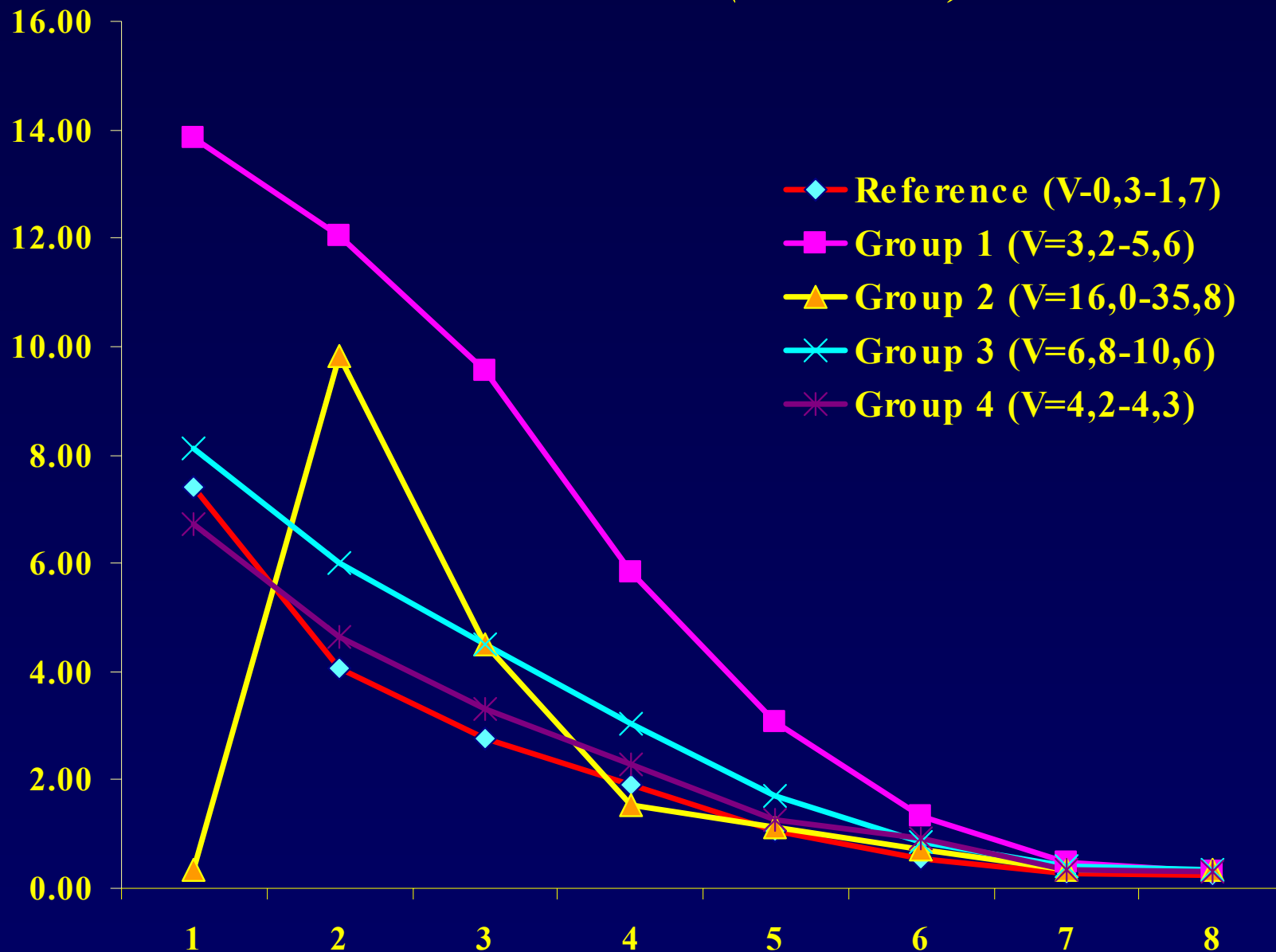
TRAINING

- **18 QA and HIV and hepatitis laboratory diagnostics training courses were held in different regions of Central Asia:**
 - Kyrgyzstan (1998, 2002, 2003)
 - Uzbekistan (1999, 2000, 2001, 2002, 2003(2),2004)
 - Kazakhstan (2000, 2001, 2002(2), 2003(2))
 - Turkmenia (2000,2004)
- **438 of participants – representatives of laboratory service system from several regions of republics**
 - Blood Donor Centers
 - Infectious diseases hospitals
 - Private laboratories
 - SSC (sanitarian surveillance centers)
- **Lecturing in quality control have been included to workshops for epidemiologists and practitioners in Central Asia**

Distribution of participants with over 70% of successful examination rate



Results of laboratorial day of quality control workshop in Tashkent (June 2002)



Reference laboratories for HIV and viral hepatitis were established in four states of Central Asia

- Kyrgyzstan (1998)
- Uzbekistan*(1999)
- Kazakhstan (2000)
- Turkmenistan (2000)

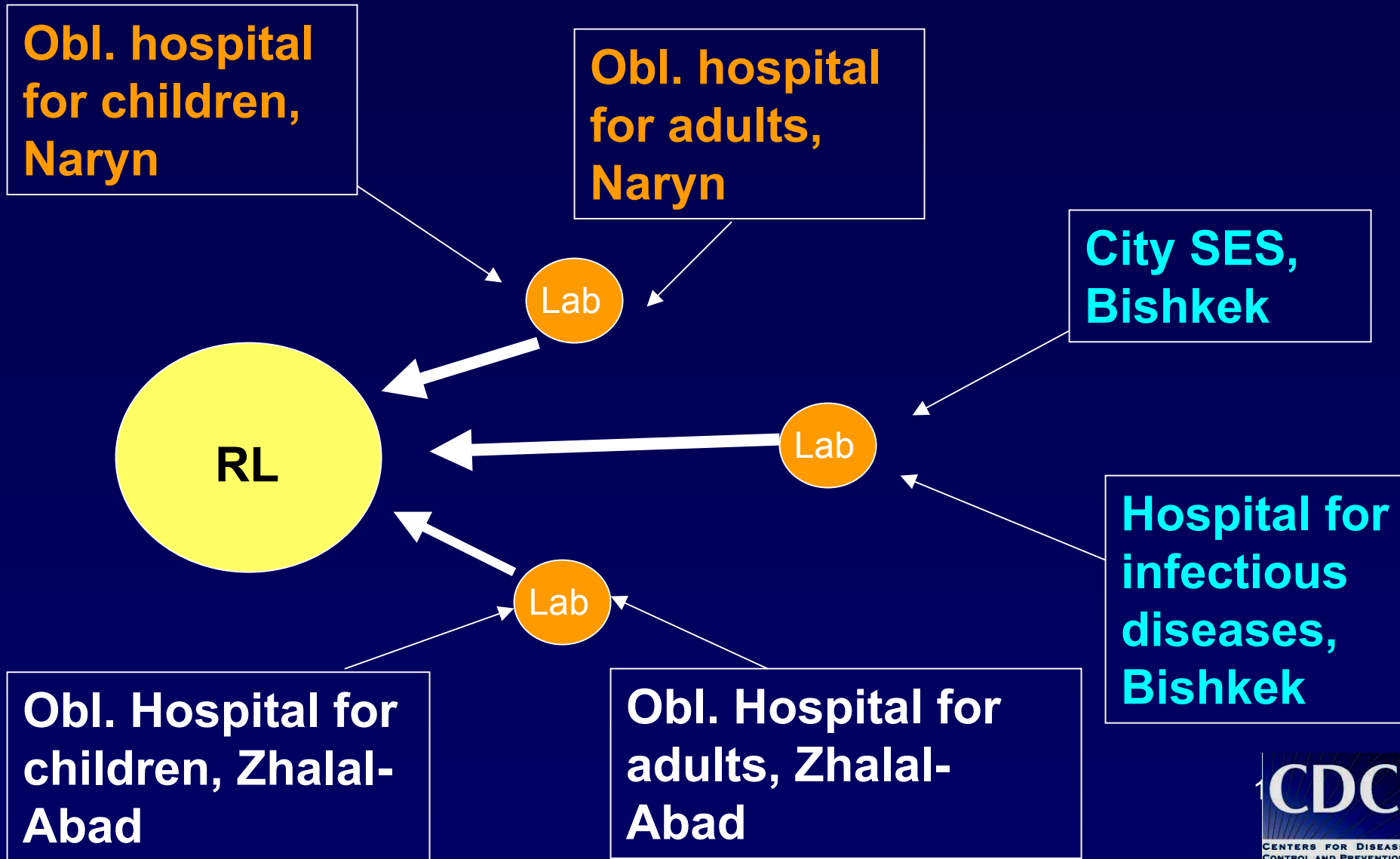
* Joint project with Swiss agency of emergent events and CDC/USAID

JURAL BASIS OF NRL

- The principals of establishing of assurance of quality control system are fixed in «Regulation of activity of reference laboratories» and approved by Ministry of Health

Implementation QA program in acute viral hepatitis sentinel surveillance in Kyrgyzstan

Organizational Scheme of preanalytical step of the research



Quality Performance of test-system on HBsAg (2000)

SHORT NAME OF THE TEST-SYSTEMS	Sensitivity		Specificity	
	Sample Correlation	%	Sample Correlation	%
«HBs антиген-ИФА»	31/31	100	0/37	0
«Рекоматгеп В-стрип»	23/31	74,1	49/50	98
«Вектогеп В- HBsAg-стрип»	25/31	80,6	50/50	100
«Рекоматгеп В-стрип»	31/31	100	33/50	66
«ИФА-HBsAg/м»	30/31	97	50/50	100
HBsAg-ИФА	22/31	70,9	50/50	100

The evaluation of the quality assurance systems effectiveness for the laboratory researches in Sentinel Epidemiologic Surveillance of Kyrgyzia

was conducted by repeated research of 25% of the samples in the reference-laboratory for virus hepatitis diagnosis in CDC Atlanta

Results of data comparison from RL of Kyrgyzia and RL of CDC Atlanta (2002)

Marker	Presence of the marker	CDC Data	RL data	
			Number of correct	Number of errors
anti-BГА IgM	positive	355	352	3
	negative	237	222	15
	total	592	574	18 (3,0%)

Results of data comparison from RL of Kyrgyzia and RL of CDC Atlanta (2002)

Marker	Presence of the marker	CDC Data	RL data	
			Number of correct	Number of errors
Anti-HCV	positive	59	46	13
	negative	544	534	10
	total	603	540	23 (3,8%)

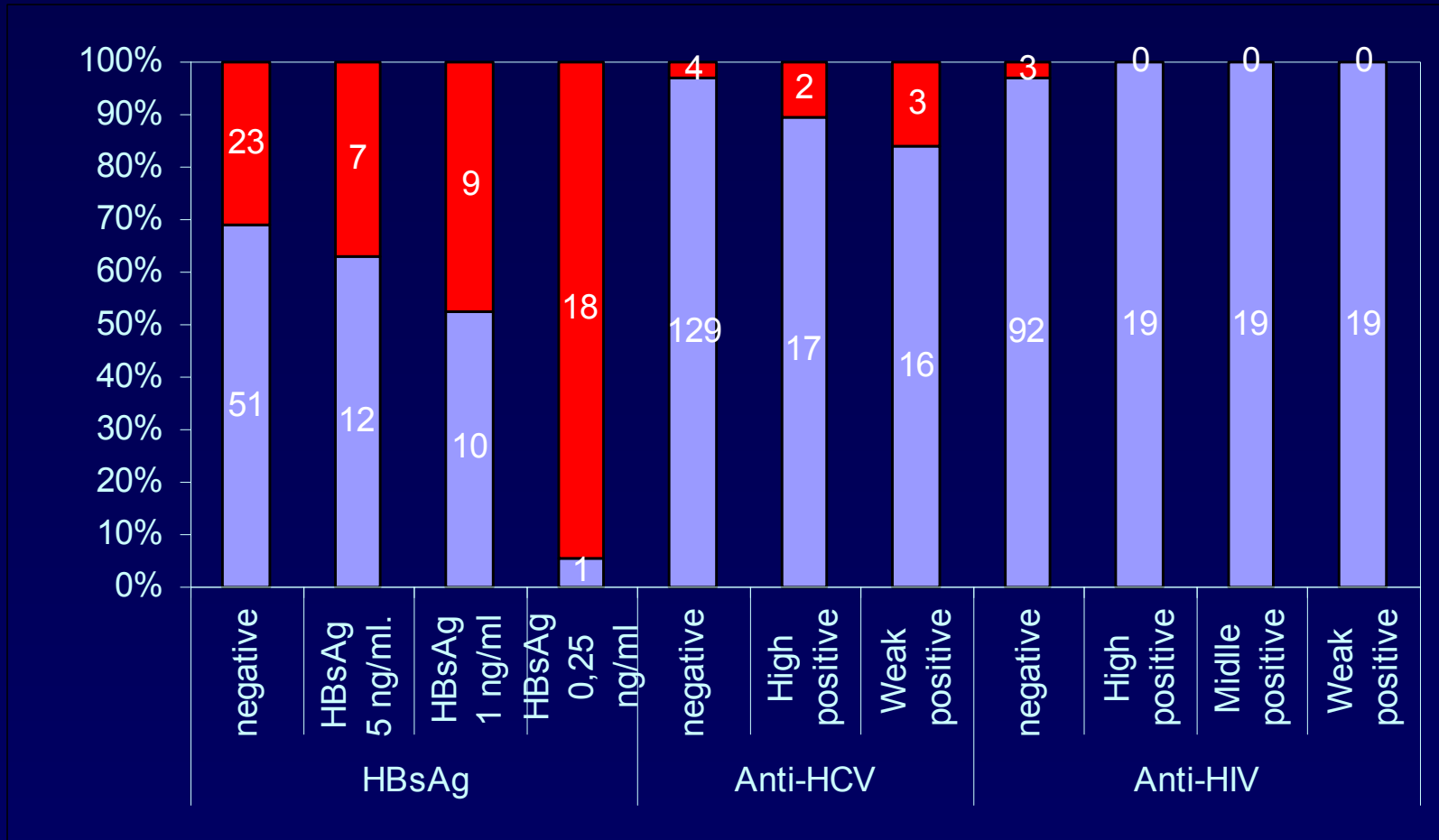
Results of data comparison from RL of Kyrgyzia and RL of CDC Atlanta (2002)

Marker	Presence of the marker	CDC Data	RL data	
			Number of correct	Number of errors
anti-HBcor IgM	positive	159	125	34
	negative	285	251	7
	total	417	376	41 (9,8%)

Results of data comparison from RL of Kyrgyzia and RL of CDC Atlanta (2002)

Marker	Presence of the marker	CDC Data	RL data	
			Number of correct	Number of errors
HBsAg	positive	243	172	71
	negative	347	343	4
	total	590	515	75 (12,7%)

EQC Results of 19 laboratories of AIDS Centers of Kazakhstan (2002)



Conclusion (1)

- **The program of quality assurance of laboratory diagnosing of HIV and viral hepatitis has been developed and implemented in Uzbekistan, Kazakhstan and Kyrgyzstan**
- **The realization of program allowed:**
 - Training the rules of quality assurance to laboratory experts of Central Asia
 - Obtaining the objective results of monitoring of viral hepatitis in Kyrgyzstan
 - Organization of quality control of test kits while licensing and further production in Uzbekistan and Kirghizia
 - Monitor the quality of testing of HBsAg, anti-HCV, anti-HIV while EQC in Uzbekistan, Kazakhstan and Kyrgyzstan

Conclusion (2)

- **The QA will be improved by:**
 - **Implementation of the national External Quality Control programs on the regular basis**
(Kazakhstan, Uzbekistan)
 - **Realization of the interregional EQC programs**
(NRL of AIDS Centers of Kazakhstan and Kyrgyzstan, 2003)
 - **Participation in the international EQC programs**
 - **MPEP, Atlanta CDC, 2004** *(Kazakhstan 6: Uzbekistan-10: Kyrgyzia -1)*
 - **PTP anti-HIV DBS, CDC Atlanta, 2004**
(Kazakhstan -6 lab, Uzbekistan -1 lab, Kyrgyzia- 1 lab)

Thank you for your attention