RESULT OF THE NATIONAL EXTERNAL QUALITY ASSESSMENT SCHEME OF SEROLOGY TESTS FOR IDENTIFYING TRANSFUSION-TRANSMITTED INFECTION

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BACKGROUND

- The aim of EQAS is to control the quality of laboratory testing, assess the quality control capacity, find out common problems and to increase the reliability of tests.
- The National Center for Transfusion Medicine (NCTM)

  is involved in EQAS since 2005 and NCCD- since 2011.
- NCTM and NCCD in collaboration with the Australian National Reference Laboratory for Serology (NRL) is implementing National External Quality Assessment Scheme for identifying HIV, Syphilis, HepC and HepB.

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BACKGROUND

For implement the National External Quality Assessment Scheme :

- The experts from NRL conducted several trainings and workshops for the doctors of NCCD and NCTM
- Has been established a serum stock
- All expenses related to preparation of control sample panel were covered from the project.

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MATERIALS AND METHODS:

- Organizing of EQAS, selection of samples, verification, preparation, packaging, transportation, laboratory methods, receiving of results and analyzing were performed according to the recommendations of WHO.
- The EQAS were conducted two times: in July of 2012 and March of 2013 and all results received from participating laboratories were analyzed.

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THE NATIONAL EQAS

- HIV: Anti HIV1/2
- HCV : Anti HCV
- HBV: HBsAg
- Syphilis: Ab

- To assess the quality of detection sample panel with positive and negative sample (5) were prepared.

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PARTICIPANTS IN THE NATIONAL EQAS

- 21 provinces
- 5 soums
- 9 districts
- UB 10 Hospitals

- In 2012 30 laboratories
- In 2013 45 laboratories

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RESULTS

2012.07

Infection	Samples sent to lab	Received results from	Tested
HIV	30	29 (97%)	29 (97%)
HBV	30	29 (97%)	25 (86%)
HCV	30	29 (97%)	26 (90%)
Syphilis	30	29 (97%)	29 (97%)

2013.02

Infection	Samples sent to lab	Received results from	Tested
HIV	45	45 (100%)	45 (100%)
HBV	45	43 (96%)	43 (96%)
HCV	45	43(96%)	43(96%)
Syphilis	45	44(98%)	44(98%)

RESULTS(ANTI HIV ½)

	2012.07	2013.02
Laboratories sent the results	**29 (96.7%)**	**45 (100%)**
Laboratories did not send the results	**1 (3.3%)**	**-**
Correct	**28 (96.6%)**	**44 (97.8%)**
Incorrect	**1 (3.4%)**	**1 (2.2%)**
Laboratories used expired test kits	**-**	**1 (2.2%)**

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RESULTS(HIV 2013.02)

Lab ID	kit's name	А	Б	В	Г	Д
	Correct result	negative	positive	negative	Negative	Negative
1000	Genedia HIV 1/2 Rapid 3.0	negative	positive	positive	negative	Negative
	Genedia HIV 1/2 Elisa 3,0	negative	positive	positive	negative	Negative

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RESULTS (HIV 2013.02)

	Method	Number	Percentage	
Multiple	Rapid, PA, ELISA	3	6.7%	40.0%
	ELISA, Rapid	6	13.3%	
	PA, Rapid	9	20.0%	
Only one method	ELISA	3	6.7%	60.0%
	Chemiolumin	1	2.2%	
	Rapid	23	51.1%	
Total		45		100%

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RESULTS(SYPHILISTP)

	2012.07	2013.02
Laboratories sent the results	**29 (96.7%)**	**44 (97.8%)**
Laboratories did not send the results	**1 (3.3%)**	**1 (2.2%)**
Correct	**25 (86.2%)**	**42 (95.5%)**
Incorrect	**4 (13.8%)**	**2 (4.5%)**
Laboratories used expired test kits	**1 (3.3%)**	**-**

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RESULTS(SYPHILISTP)

	2012.07	2013.02	
Method	TPHA	TPHA	Rapid test
Laboratories tested incorretly	4	1	1
False negative	1	1	1
False positive	2	0	0
Unclear	1	0	0
Total	**4 (13.8%)**	**2 (4.5%)**	

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RESULTS(HBV)

	2012.07	2013.02
Laboratories sent the results	**25 (83.3%)**	**43 (95.6%)**
Laboratories did not send the results	**5 (16.7%)**	**2 (4.4%)**
Correct	**25 (100%)**	**42 (95.5%)**
Incorrect	**-**	**2 (4.5%)**
Laboratories used expired test kits	**-**	**-**

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HBV 2013.02 INCORRECT RESULTS

Lab ID	kit's name	А	Б	В	Г	Д
correct result		positive	positive	positive	positive	negative
1700	Genedia HbsAg ELISA 3.0	Insufficient amount of serum	positive	positive	positive	negative
	Genedia HbsAg rapid device	Insufficient amount of serum	positive	positive	positive	negative
2014	Genedia HbsAg ELISA 3.0	positive	positive	positive	positive	unclear
2100	Foresight EIA test kit HbsAg	20,804	16,	17,008	17,785	0,099

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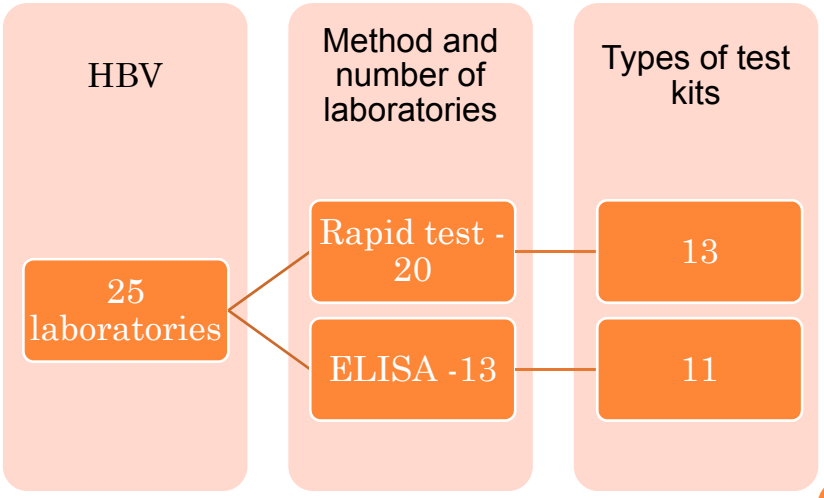
RESULTS OF HBV 2012.07



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RESULT (HCV)

	2012.07	2013.02
Laboratories sent the results	26 (86.7%)	43 (95.6%)
Laboratories did not send the results	4 (13.3%)	2 (4.4%)
Correct	26 (100%)	41 (95.4%)
Incorrect	-	2 (4.6%)
Laboratories used expired test kits	-	-

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RESULTS: METHOD OF ANALYSIS

	HIV		HCV		HBV		Syphilis	
Panel ID	2012.07	2013.02	2012.07	2013.02	2012.07	2013.02	2012.07	2013.02
Multiple methods	55,2%	40%	30,8%	34,8%	32%	34,8%	89,7%	81,8%
Only one method	44,8%	60%	69,2%	65,2%	68%	65,2%	10,3%	18,2%

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CONCLUSION

1. According to the results of two assessments 96.6-97.8% of laboratories tested correctly the Anti HIV ½, 95.4-100%- the Anti HCV, 95.5-100% of laboratories tested correctly the HBsAg and 86.2-95.5%- the Syphilis TP.
2. Since different laboratories use different kits the results are different.
3. In 10-69% of laboratories do not follow the algorithm and the strategy of analysis and the results of tests are given directly after the first test.
4. There is a need to strengthen laboratory analysis and strongly follow up SOPs.

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