# INTERNATIONAL SEMINAR - CONFERENCE

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Commercial Director

Novosibirsk 15 October 2013



## Welcome to Vector-Best!





## JSC Vector-Best

	1989	1992	2012
Staff	30	70	> 700
Product list	1	4	> 360
Kits per month	5 000	8 000	> 100 000



## Manufacturing building in Koltsovo





## Key ELISA products

markers of viral hepatitis

**TORCH-infections** 

parasitic diseases

oncomarkers

thyroid hormones

tick-borne encephalitis and Lyme disease

control of immune status

cytokines

allergens

cardiac





## Biochemical products

biochemical parameters

hematology

turbidimetry

standard samples

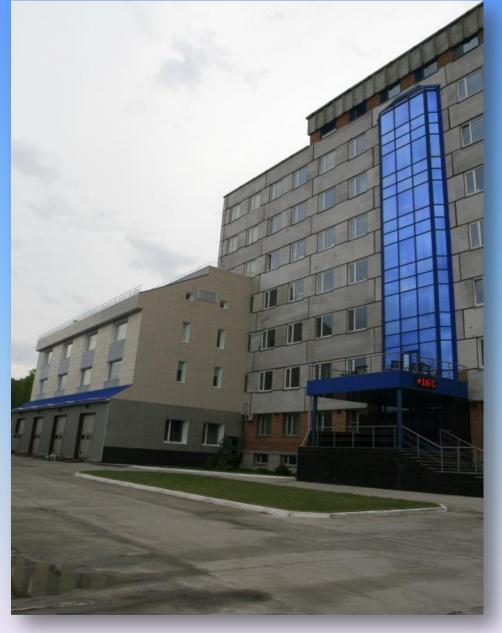
calibration materials





# Manufacturing and Laboratory Building

Novosibirsk Academtown







## Key ELISA products

HIV infection
viral hepatitis B and C
syphilis

**STI** 





## Real time PCR

HIV infection
viral hepatitis B and C
STI

**TORCH** infections

tick-borne infections

gastrointestinal disease





#### CE CERTIFICATION



Product certification body
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

#### **CERTIFICATE**

No. 11 0752 T/ITC

confirm that the products - in vitro diagnostic medical devices - according to the Directive 98/79/EC:

#### PCR kits and reagents

(For detailed description refer to Annex of this Certificate, pages 2-3)

manufactured by company

#### ZAO "Vector-Best"

#### AHC, Koltsovo, Novosibirsk Region, 630559, Russia

comply with the applicable essential requirements of the European Parliament and of the Council Directive 98/79/EC on in vitro diagnostic medical devices as amended.

Referring to the intended use, the ITC Products Certification Body has conducted with successful results the type-examination of the certified product according to the relevant parts of the above mentioned Directive and appropriate harmonized European standards.

The detailed product descriptions, documents, assessment procedures and evaluations of the examination are presented in the Final Report No. 313600261/2011, which is enclosed to this certificate.

This Certificate is issued under the following conditions:

- 1. It applies only to the above referenced models of the medical devices.
- 2. It does not imply that the ITC has performed any surveillance or control of their manufacture.
- The manufacturer is obligated to assure conformity of all in vitro diagnostic medical devices of the respective model to type assessed by the mean of this Certificate.
- The Certificate remains valid until the manufacturing conditions, the quality system or relevant legislation are changed but until the 11<sup>th</sup> September 2014 at the latest.
- After fulfilling of the relevant EU legislation requirements, the manufacturer shall affix to each in vitro diagnostic medical device, of the above referenced models, the CE-marking according to this example:

CE

Issued in Zlin, on 12th September 2011





### **EC** Certificate

#### mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

VECTOR



ZAO "Vector-Best" AHC, Koltsovo 630559 Novosibirsk region Russian Federation

for the scop

RealBest DNA Chlamydia trachomatis, RealBest DNA CMV, RealBest DNA Toxoplasma gondii, RealBest RNA Rubella

has introduced and applies a

#### Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

#### Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/EC

of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. The surveillance will be held as specified in Annex IV, Section 5.

> Valid from Valid until Registration no. Report no.

2012-07-03 2017-07-03 4112.21.01/0 E 4112.21 / 2012-07-03

71.Am

Head of Certification Body



mdc medical device certification GmbH Kriegerstraße 6 D-70191 Stuttgart, Germany Phone: +49-(0)711-253997-0 Fax: +49-(0)711-253597-10 Internet: http://www.mdc-ce.de

For electronic publication only



## ISO CERTIFICATION

Certified
Quality System



ein Unternehmen von ZDH-ZERT

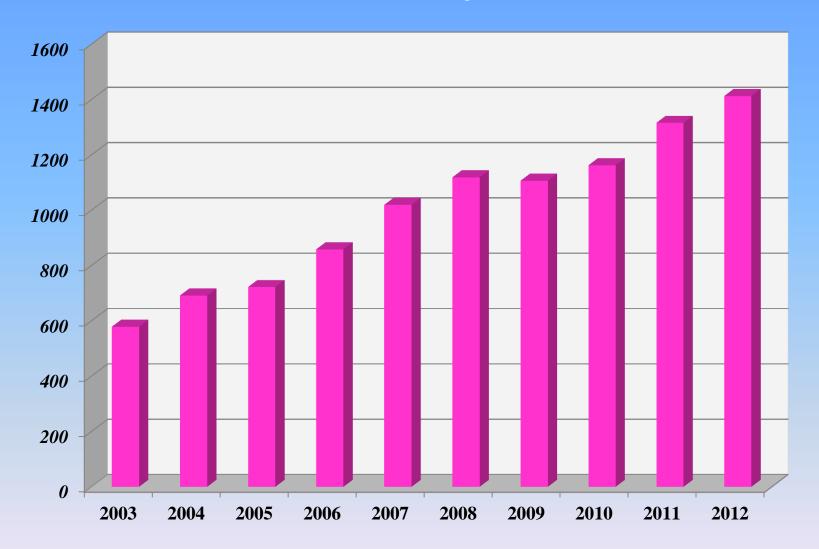
ISO 13485 ISO 9001 Zertifiziertes QM-System



ISO 13485 ISO 9001

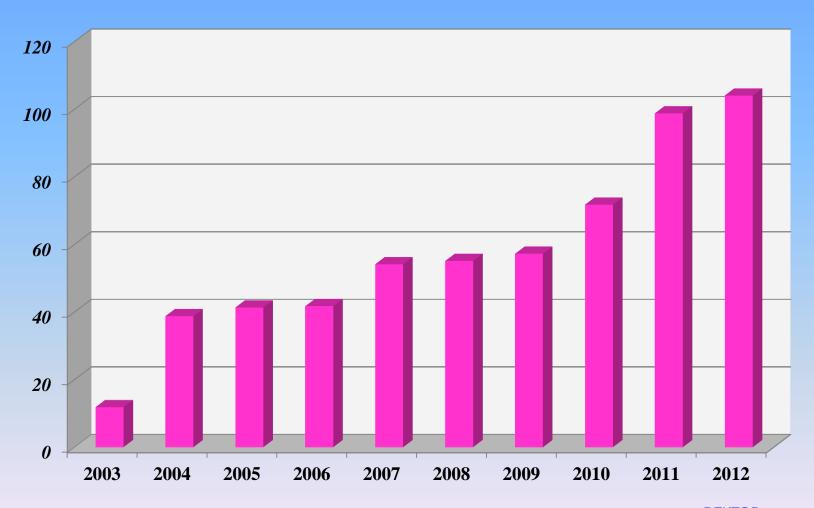


## SALE (thousand of kits)





## EXPORT (thousand of kits)



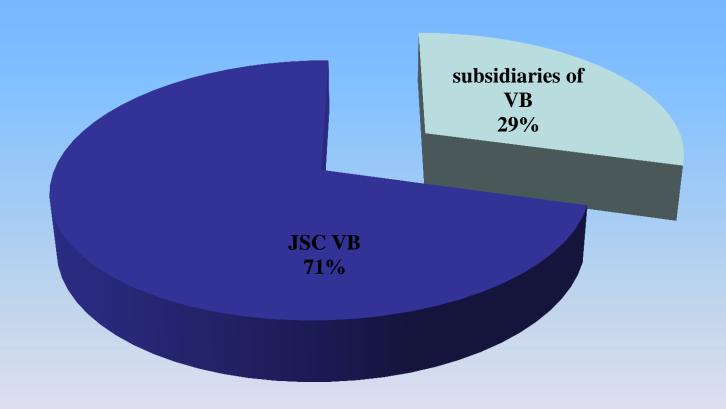


## Location of Vector-Best Holding





## NET ASSET VALUE of VB HOLDING (51.4 million €)







62.6 million € - total gross sales of reagents for immunochemistry in 2012





