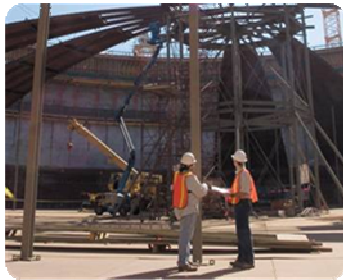


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# Pathogen Asset Control System (PACS) Concept & Capabilities

September 21, 2009  
Irkutsk, Russia

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# PACS Definition

The Pathogen Asset Control System (PACS) is a tool used for accounting and control of bioagent stocks managed by biological laboratories.

PACS provides a secure, reliable, timely method of monitoring and tracking the flow of biological agents as well as extended audit and reporting functionality.



# Background and Technologies

PACS is developed specifically for laboratories that manage biological agent collections in accordance with their business-processes and rules & regulations.

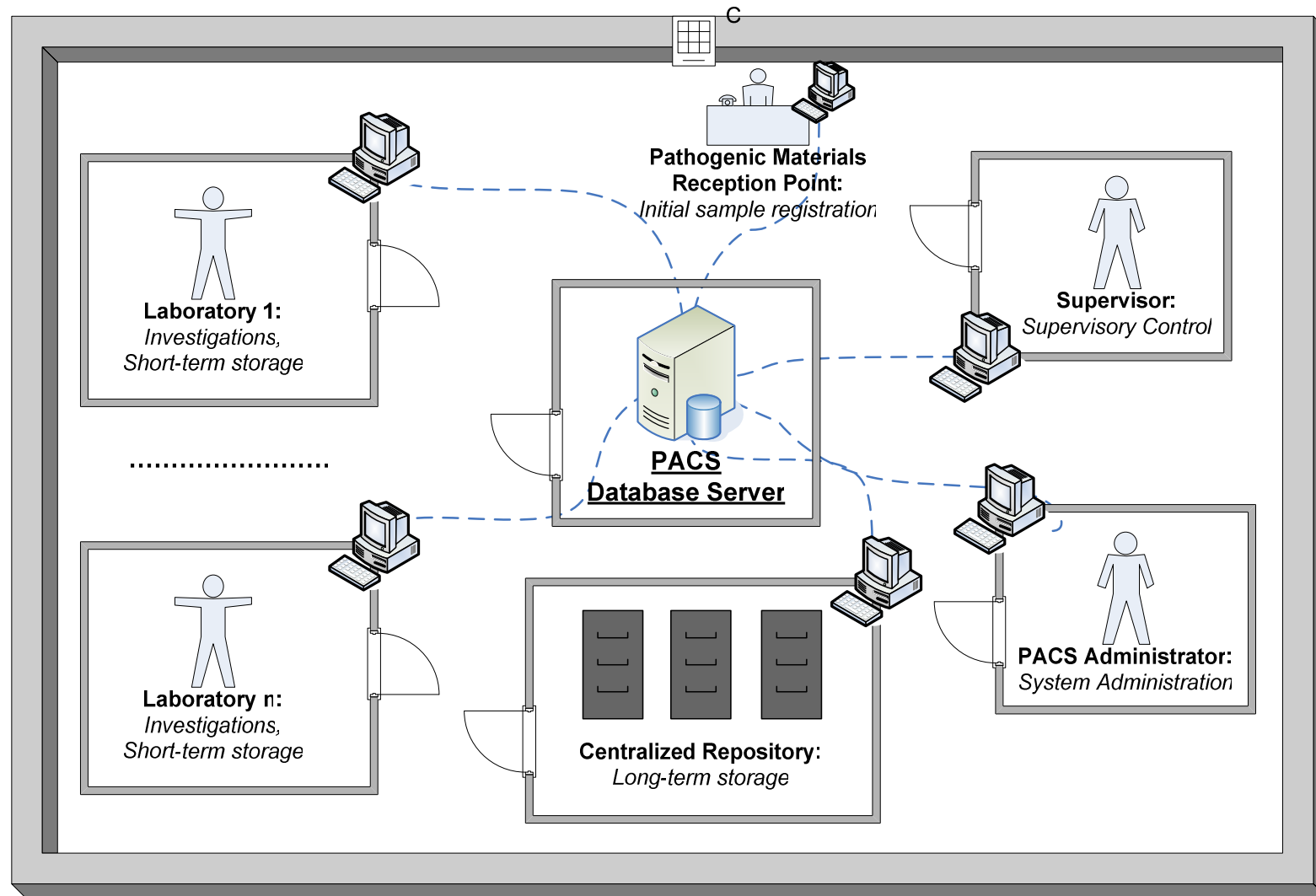
The system supports all the main processes performed for collection maintenance and management. The initial approach was to track only isolated strains stored in centralized repositories however (after several development stages) PACS is now being utilized as a convenient and reliable tool for tracking and accounting all kinds of biological materials including samples, isolates, strains, etc.

There are two possible types of PACS installations: *standalone* for centralized collections and *networked* for the facilities with several pathogen storage areas.

PACS was developed using the latest industry standard technologies such as Microsoft Visual Studio .NET, Windows XP Professional / Vista, SQL Server 2000-2005.

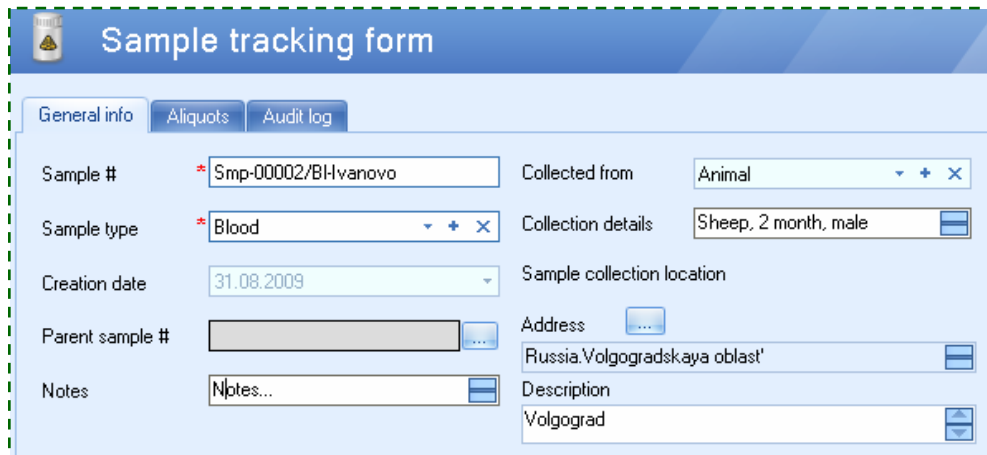
Using .NET connected technology allows the PACS application to take full advantage of Windows XP Professional / Vista and SQL Server 2000-2005 features such as a *high level of security, and scalability*. Using these leading class technologies ensures that PACS is reliable and supportable for the long term.

# Concept of Operations



## Capabilities: Core System Features

- Tracks all kinds of **samples** and isolated **strains**



Sample tracking form

General info Aliquots Audit log

Sample # \* Smp-00002/BHvanovo Collected from Animal

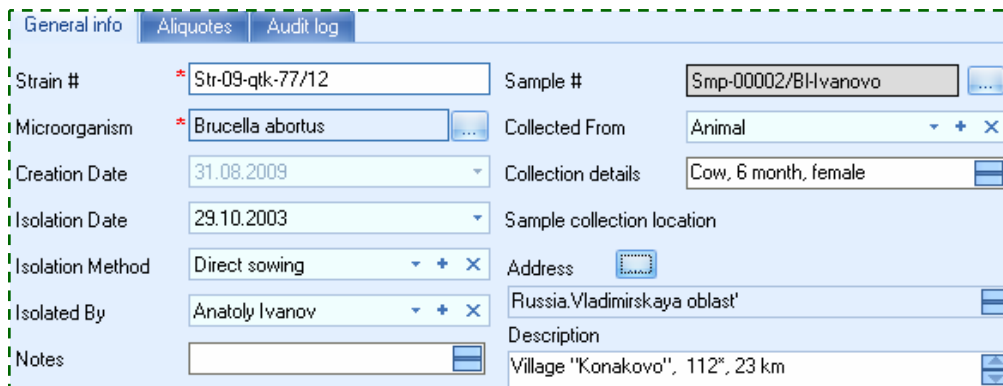
Sample type \* Blood Collection details Sheep, 2 month, male

Creation date 31.08.2009 Sample collection location

Parent sample # Address Russia.Volgogradskaya oblast'

Notes Nptes... Description Volgograd

- Excellent performance characteristics with more than **5 mln records** in database



General info Aliquots Audit log

Strain # \* Str-09-qtk-77/12 Sample # Smp-00002/BHvanovo

Microorganism \* Brucella abortus Collected From Animal

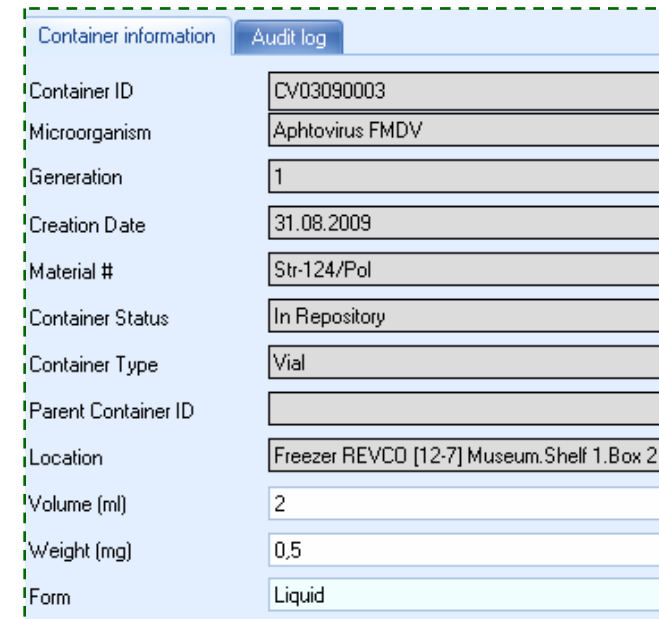
Creation Date 31.08.2009 Collection details Cow, 6 month, female

Isolation Date 29.10.2003 Sample collection location

Isolation Method Direct sowing Address Russia.Vladimirskaia oblast'

Isolated By Anatoly Ivanov Description Village 'Konakovo', 112°, 23 km

Notes



Container information Audit log

Container ID CV03090003

Microorganism Aphthovirus FMDV

Generation 1

Creation Date 31.08.2009

Material # Str-124/Pol

Container Status In Repository

Container Type Vial

Parent Container ID

Location Freezer REVCO [12-7] Museum.Shelf 1.Box 2

Volume (ml) 2

Weight (mg) 0,5

Form Liquid

## Capabilities: Core System Features

- Detailed sample/strain **catalogs** with a quick search panel

Organism Name	Passport Number	Receive Date
Yersinia pestis	Y.p. - II - IV - 012	01.08.2008
Aphthovirus FMDV	FMDV-93-19-001	01.08.2008
Vibrio cholerae 01	V.ch./11/03/86	06.08.2008
Brucella abortus	B.a. 159-21-11	08.08.2008
Brucella abortus	Br.a.09k-92-002	21.08.2008
Brucella melitensis	Br.m-09d-77-0913	23.08.2008
Bacillus anthracis	B.a.-dt-001-17	25.08.2008
Brucella suis	Br.s.-II-0243	25.08.2008
Vibrio cholerae 01	V.ch.01-3298-1	26.08.2008
Bacillus anthracis	Br.a-9324-ka	29.08.2008
Brucella abortus	GV1108000E	29.08.2008

Strain #

Container ID

Microorganism

Creation Date: From:  To:

Isolation Date: From:  To:

Isolation Method

Isolated By

Sample #

Sample Collected From

Sample Collection Details

- Powerful **search engine** for custom search and reporting

Pathogen Asset Control System - [Search Template]

### Search Template

Template name:

Set criteria by object:

Isolation method:

Search criteria:

Columns to display: ☒ Strain #  
☐ Isolated by  
☐ Notes  
☐ Collected from  
☒ Microorganism  
☒ Isolation method  
☐ Sample collection location address  
☐ Sample

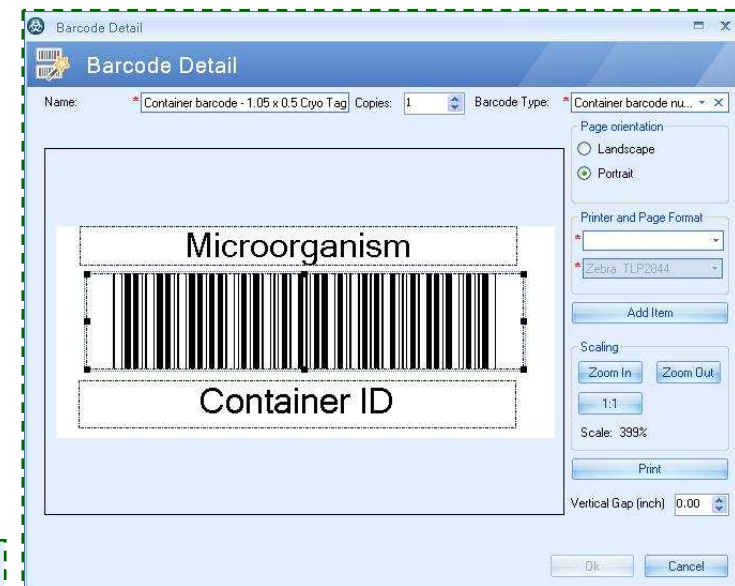
Search results:

Strain #	Microorganism	Isolation method
> Str-09-qtk-77/12	Brucella abortus	Direct sowing

Found: 1 records

## Capabilities: Core System Features

- Utilization of **Barcode Technology** (mechanical/chemical/temperature highly resistant barcode labels)
- **Unique auto-generated ID's** (on barcode labels) for all individual containers (aliquots) according customizable, pre-defined Object Numbering Schema
- **Barcode Label Designer** allows creating custom barcode labels
- Tracks **absolute location for each individual container**



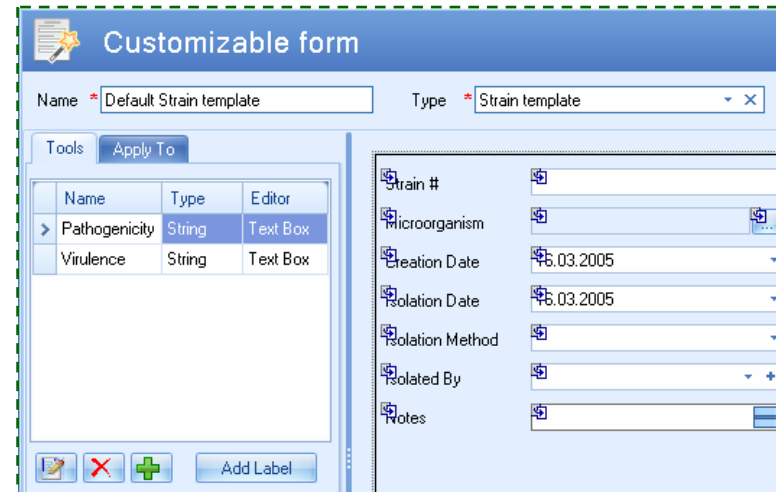
Location

Freezer REVCO [12-7] Museum.Shelf 1.Box 2



## Capabilities: Core System Features

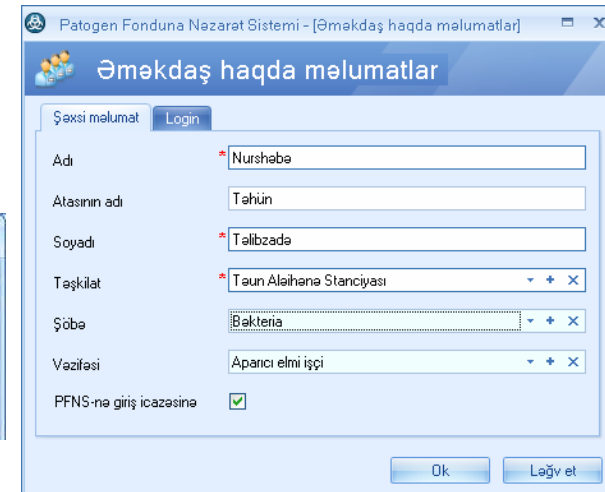
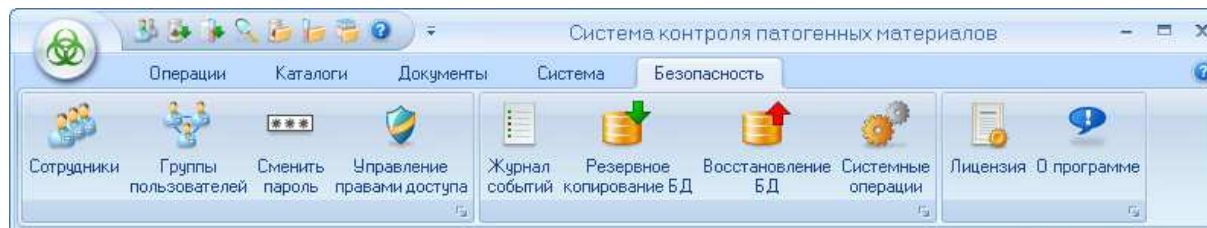
- **Customizable Forms Editor** allows customization of sample/strain tracking forms to record all necessary properties/characteristics
- **Fully multi-lingual application:** interfaces, database, reports as well as user documentation and training materials



The screenshot shows a window titled "Customizable form". It has a "Name" field with "Default Strain template" and a "Type" dropdown menu set to "Strain template". Below this is a "Tools" section with an "Apply To" button and a table:

Name	Type	Editor
Pathogenicity	String	Text Box
Virulence	String	Text Box

At the bottom of the table are icons for adding, deleting, and creating new items, along with an "Add Label" button. To the right of the table is a list of form fields for a strain template, including "Strain #", "Microorganism", "Creation Date" (set to 16.03.2005), "Isolation Date" (set to 16.03.2005), "Isolation Method", "Isolated By", and "Notes".



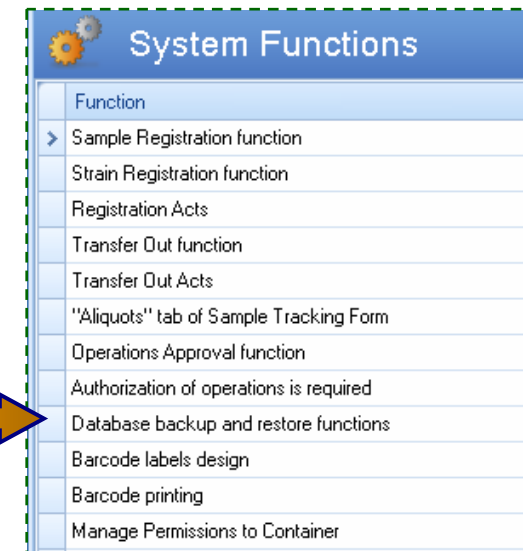
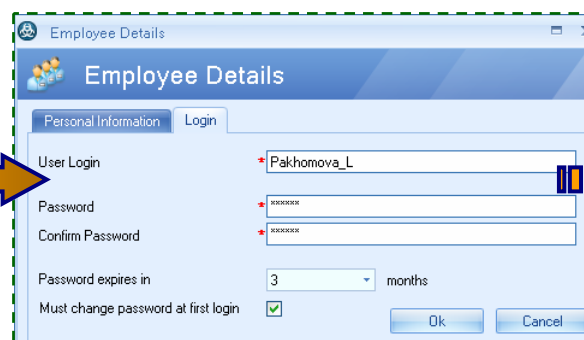
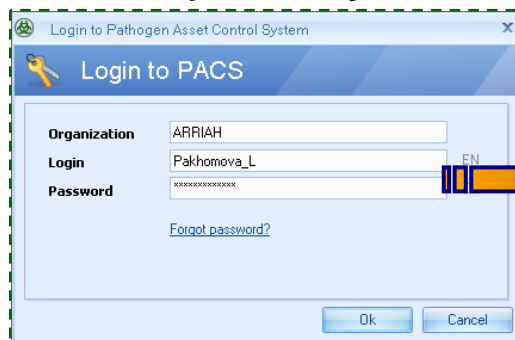
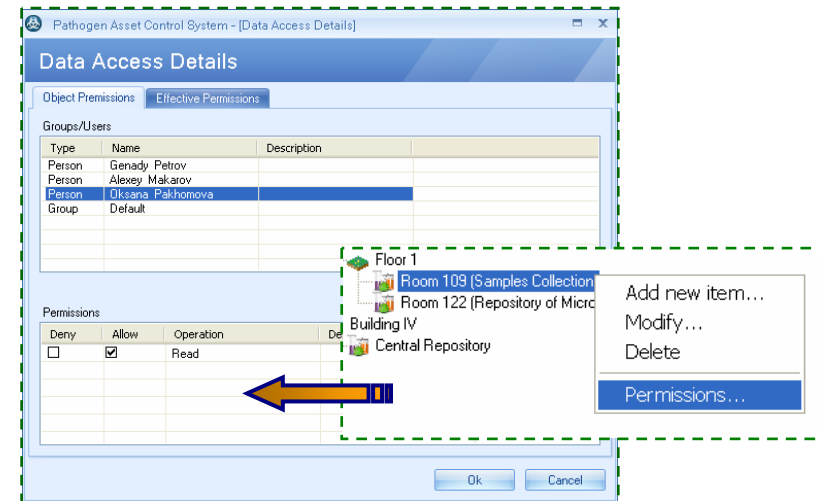
The screenshot shows a login form titled "Patogen Fonduna Nəzarət Sistemi - [Əməkdaş haqda məlumatlar]" (Pathogenic Material Control System - [Employee information]). It has a "Şəxsi məlumat" (Personal information) section with a "Login" button. The fields are:

- Adı (Name): Nurshəbə
- Atasının adı (Father's name): Təhün
- Soyadı (Surname): Təlibzadə
- Təşkilat (Organization): Təbii Aləmlərin Stansiyası
- Şöbə (Department): Bakteriya
- Vəzifəsi (Position): Aparıcı elmi işçi
- PFNS-ə giriş icazəsinə (Access to PFNS): [checked]

At the bottom are "Ok" and "Ləğv et" (Cancel) buttons.

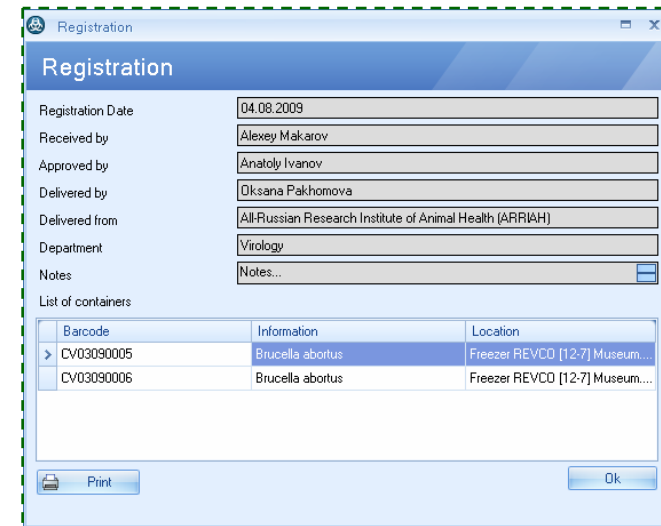
## Capabilities: Security Features

- Highly customizable multilevel **Data Access System** based on Individual User Accounts (login / password / organization). Access can be restricted:
  - **By Functions**, i.e. user can utilize certain set of system functions according his role and responsibility
  - **By Data Segments**, i.e. user can see information only on certain microorganisms or certain place in repository



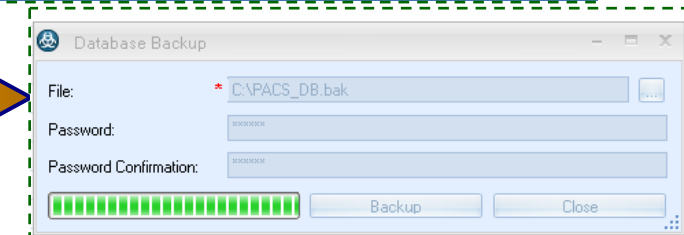
## Capabilities: Security Features

- **System Event Log**: tracking of all operations in the system. Date/time, operator, type of operation and details recorded
- Detailed **Audit Log for every sample/strain** and its aliquots: every data field change is tracked to meet all regulatory requirements
- Password protected database **Backup and Recovery**
- **Automatic system lock** when user is idle
- **No external data channels**: secure standalone or dedicated network configuration
- User **password expiration**

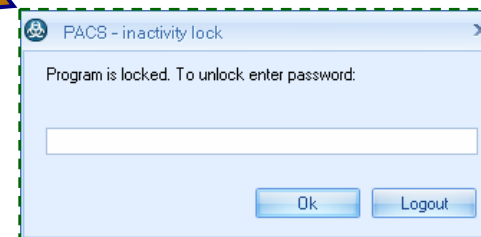


Registration window showing fields for Registration Date, Received by, Approved by, Delivered by, Delivered from, Department, Notes, and a List of containers table.

Barcode	Information	Location
CV03090005	Brucella abortus	Freezer REVC0 [12-7] Museum...
CV03090006	Brucella abortus	Freezer REVC0 [12-7] Museum...



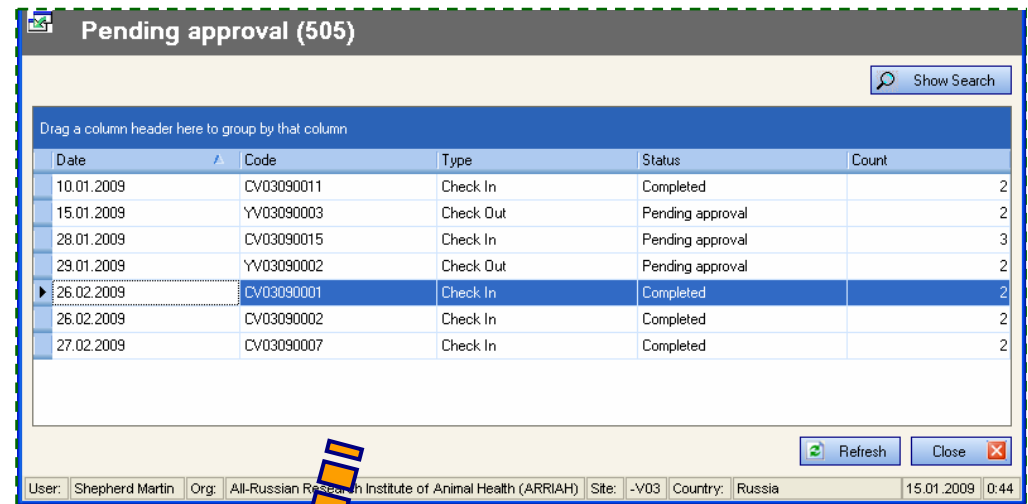
Database Backup window showing File, Password, and Password Confirmation fields, along with a progress bar and Backup/Close buttons.



PACS - inactivity lock window showing a message: "Program is locked. To unlock enter password:" and a password input field with Ok/Logout buttons.

## Capabilities: Security Features

- **Operations Authorization Feature:** system can be configured to require authorization of certain operations. Unauthorized operations can not be completed and containers involved are automatically blocked. Supervisor uses “Journal of Operations pending approval” to Approve or Decline operations after review



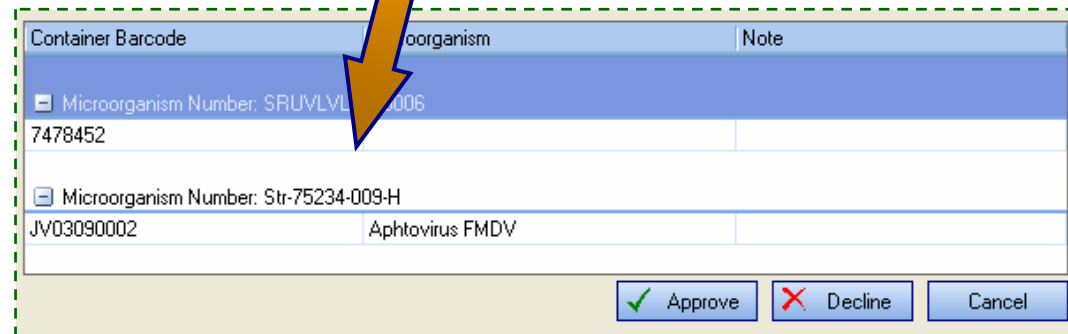
Pending approval (505)

Drag a column header here to group by that column

Date	Code	Type	Status	Count
10.01.2009	CV03090011	Check In	Completed	2
15.01.2009	YV03090003	Check Out	Pending approval	2
28.01.2009	CV03090015	Check In	Pending approval	3
29.01.2009	YV03090002	Check Out	Pending approval	2
26.02.2009	CV03090001	Check In	Completed	2
26.02.2009	CV03090002	Check In	Completed	2
27.02.2009	CV03090007	Check In	Completed	2

Refresh Close

User: Shepherd Martin Org: All-Russian Research Institute of Animal Health (ARRIAH) Site: -V03 Country: Russia 15.01.2009 0:44



Container Barcode Microorganism Note

Microorganism Number: SRUVLVL 006  
7478452

Microorganism Number: Str-75234-009-H  
JV03090002 Aphtovirus FMDV

Approve Decline Cancel

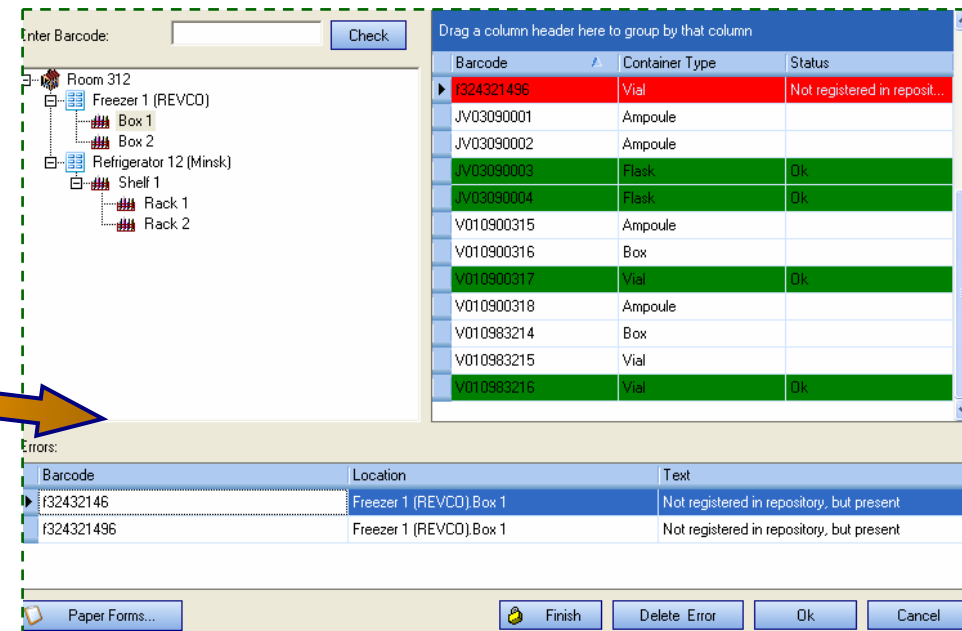
## Capabilities: Operational Features

- Sample/Strain **Registration**, **Transfer out** and **Destruction**: easy and accurate processes
- Registration / Transfer Out / Destruction **Acts** are automatically created

- **Batch information update** for fast data processing (sample / strain / container information)

## Capabilities: Operational Features

- **Inventory / Audit:** the whole repository or specific part can be inventoried. System allows to check not only existence of pathogens but also correctness of their location



Enter Barcode:  Check

Room 312

- Freezer 1 (REVC0)
  - Box 1
  - Box 2
- Refrigerator 12 (Minsk)
  - Shelf 1
    - Rack 1
    - Rack 2

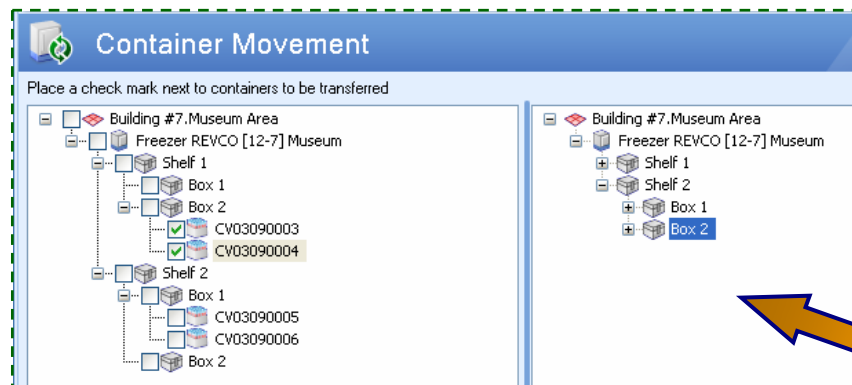
Drag a column header here to group by that column

Barcode	Container Type	Status
f324321496	Vial	Not registered in reposit...
JV03090001	Ampoule	
JV03090002	Ampoule	
JV03090003	Flask	Ok
JV03090004	Flask	Ok
V010900315	Ampoule	
V010900316	Box	
V010900317	Vial	Ok
V010900318	Ampoule	
V010983214	Box	
V010983215	Vial	
V010983216	Vial	Ok

Errors:

Barcode	Location	Text
f32432146	Freezer 1 (REVC0) Box 1	Not registered in repository, but present
f324321496	Freezer 1 (REVC0) Box 1	Not registered in repository, but present

Paper Forms... Finish Delete Error Ok Cancel



Container Movement

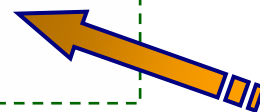
Place a check mark next to containers to be transferred

Building #7. Museum Area

- Freezer REVCO [12-7] Museum
  - Shelf 1
    - Box 1
    - Box 2
    - CV03090003
    - CV03090004
  - Shelf 2
    - Box 1
    - Box 2
    - CV03090005
    - CV03090006

Building #7. Museum Area

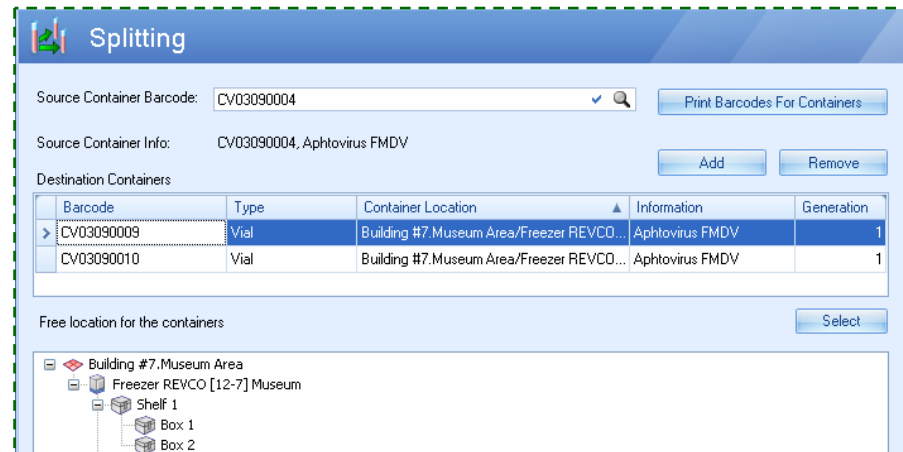
- Freezer REVCO [12-7] Museum
  - Shelf 1
  - Shelf 2
    - Box 1
    - Box 2



- **Container Movement:** allows to transfer individual containers as well as subdivisions from one place of repository to another

## Capabilities: Operational Features

- Biological material **Splitting**: biological materials can be split into two or more pieces
- Microorganism **Re-culturing**



**Splitting**

Source Container Barcode: CV03090004

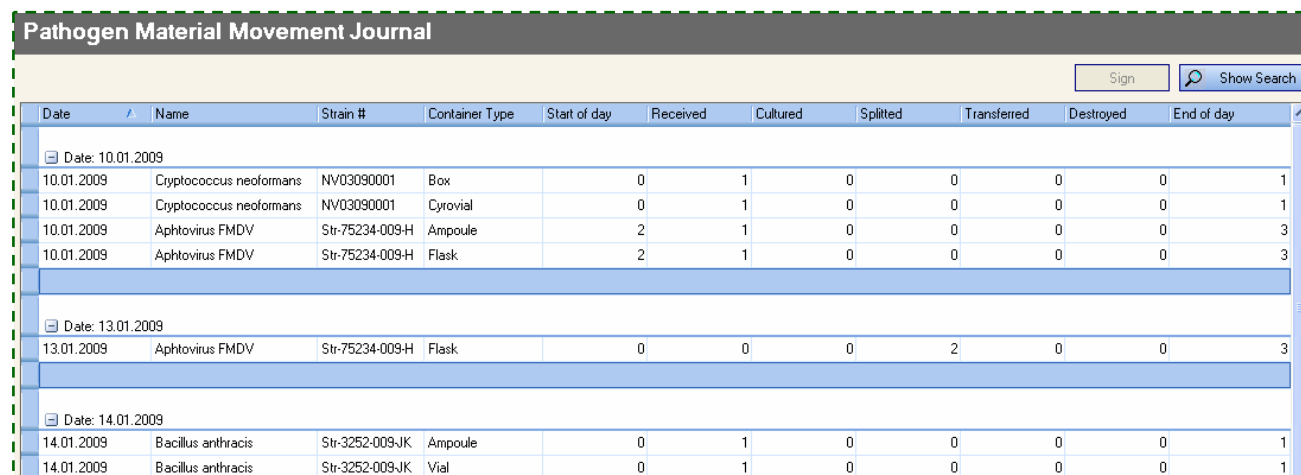
Source Container Info: CV03090004, Aphthovirus FMDV

Barcode	Type	Container Location	Information	Generation
CV03090009	Vial	Building #7, Museum Area/Freezer REVC...	Aphthovirus FMDV	1
CV03090010	Vial	Building #7, Museum Area/Freezer REVC...	Aphthovirus FMDV	1

Free location for the containers

- Building #7, Museum Area
  - Freezer REVC [12-7] Museum
    - Shelf 1
      - Box 1
      - Box 2

- **Pathogen Movement Journal**: incorporates full details of information on all operations related to container count change

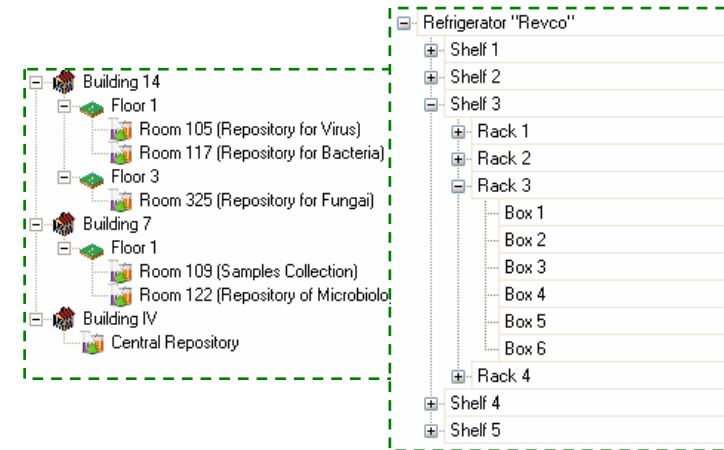


**Pathogen Material Movement Journal**

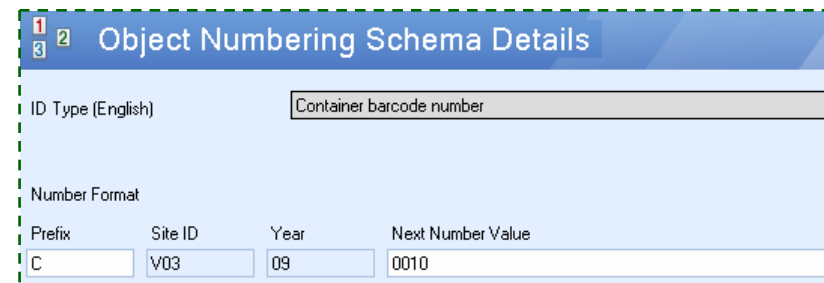
Date	Name	Strain #	Container Type	Start of day	Received	Cultured	Split	Transferred	Destroyed	End of day
Date: 10.01.2009										
10.01.2009	Cryptococcus neoformans	NV03090001	Box		0	1	0	0	0	1
10.01.2009	Cryptococcus neoformans	NV03090001	Cyrovial		0	1	0	0	0	1
10.01.2009	Aphthovirus FMDV	Str-75234-009-H	Ampoule		2	1	0	0	0	3
10.01.2009	Aphthovirus FMDV	Str-75234-009-H	Flask		2	1	0	0	0	3
Date: 13.01.2009										
13.01.2009	Aphthovirus FMDV	Str-75234-009-H	Flask		0	0	0	2	0	3
Date: 14.01.2009										
14.01.2009	Bacillus anthracis	Str-3252-009-JK	Ampoule		0	1	0	0	0	1
14.01.2009	Bacillus anthracis	Str-3252-009-JK	Vial		0	1	0	0	0	1

## Capabilities: System Administration

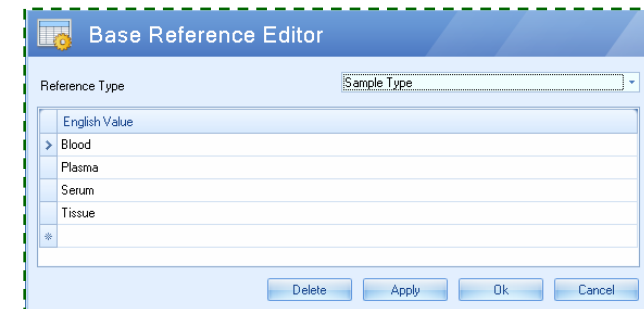
- **Detailed repository schema:**  
mimics real configuration of the repository and then exact location for each container are easily assigned



- **Object Numbering Schema:**  
guarantees uniqueness and user defined descriptions on barcode labels



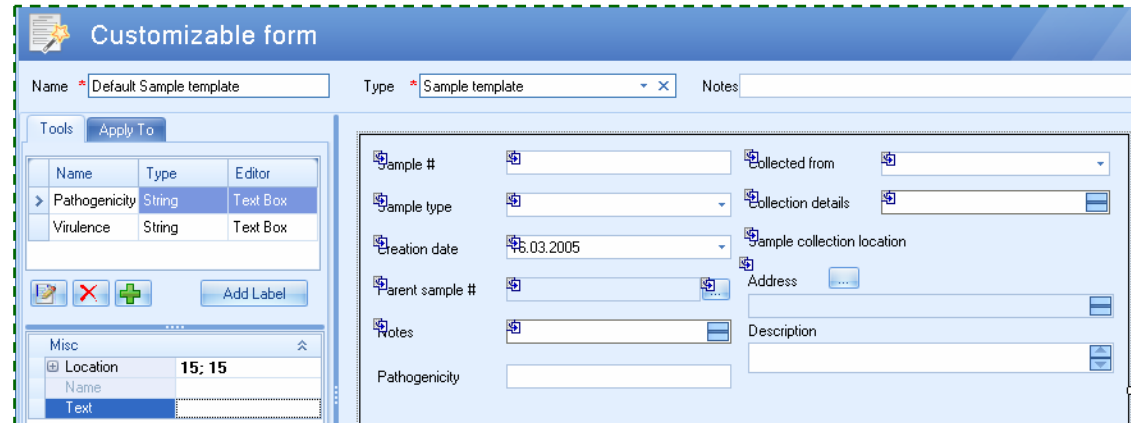
- **Base Reference Editor:**  
manages all drop-down lists to increase accuracy and simplicity of data entry process



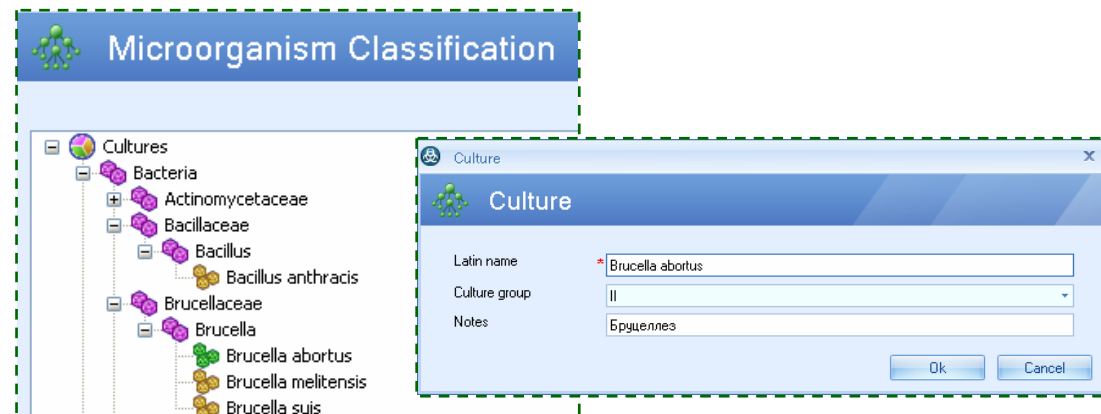


## Capabilities: System Administration

- **Customizable Forms**: allows designing data entry forms to ensure data consistency, order and completeness.
- **Microorganism tree**: internationally recognized taxonomic classification for microorganisms (...Family->Genus->Species...)
- **User Accounts / User Roles**: can be managed from single point (or distributed) by system administrator to guarantee correctness or access rights for every user






Name	Type	Editor
Pathogenicity	String	Text Box
Virulence	String	Text Box



## Capabilities: Reporting features

**Extensive reporting functions** allow users to get information from the system under different and convenient formats, including export to the most widely used file formats (doc, xls, pdf etc.):

Print Date:	04.08.2009	<b>Strain Tracking Form</b> All-Russian Research Institute of Animal Health (ARRIAH)			
Print Time:	22:31:55				
		Strain #	 Str-982/NPQ		
Microorganism:	Brucella abortus	Sample #	Smp-00002/BI-Ivanovo		
Creation date:	04.08.2009	Collected from:	Animal		
Isolation date:	04.08.2009	Collection details:	Cow, 6 month, male		
Isolation method:	Direct sowing	Sample collection location:	Russia.Krasnodarskiy kray.Labinsk		
Isolated by:	Makarov Alexey				
<b>Aliquots</b>					
<b>Container ID</b>		<b>Creation date</b>	<b>Location</b>	<b>Type</b>	<b>Status</b>
 CV03090005		04.08.2009	Freezer REVC0 [12-7] Museum.Shelf 2.Box 1	Vial	In Repository
 CV03090006		04.08.2009	Freezer REVC0 [12-7] Museum.Shelf 2.Box 1	Vial	In Repository

## Capabilities: Reporting features

### List of printable reports in PACS

- Sample Tracking Form
- Strain Tracking Form
- Container Tracking Form
- Registration Act
- Transfer Out Act
- Destruction Act
- Inventory Audit report
- Event Log
- Pathogen Movement Journal
- Audit logs for Strain/Sample/Container
- Sample List
- Strain List
- Registration Book of Materials
- Repository Subdivision Content
- Sample Containers Location
- Strain Containers Location
- *Custom* Barcode Labels
- *Custom* Search Outputs

## Features List

### Core system features

- Tracks all kinds of bioagents
- Supports more than 5 mln records
- Standalone or networked (client/server)
- Supported OS: Windows XP, Vista
- Utilizes barcode technology
- Fully multilingual
- Batch information entry and update
- Sample-Strain-Aliquots traceability
- Powerful search engine: custom queries
- Tracks absolute locations of vials
- User defined fields and field types

### Administration

- Repository Configuration
- Barcode Label Designer
- Customizable Forms Editor
- Microorganism Classification
- Geographical Location
- Base References Editor
- Object Numbering System

### Operational features

- Sample/Strain registration (all types)
- Material Transfer Out
- Material Destruction
- Vials/Containers Movement
- Repository Inventorying/Auditing
- Vial Splitting
- Re-Culturing/Maintenance

### Security

- System Events Log for all operations
- Audit Trail for every sample/strain
- Rapid Repository Inventorying
- Data Access Management
- Employees Management
- Database Backup/Restore
- Remote supervisory control
- System lock (when user is idle)

### Reporting

- Pre-defined and configurable reports
- Printing, export: Excel, Pdf, Word...

## Summary

### Pathogen Asset Control System (PACS) is

- ✓ Important part of a comprehensive Biosecurity solution
- ✓ Secure and reliable
- ✓ Sustainable and Scalable
- ✓ Highly customizable to owner's conditions
- ✓ Powerful and helpful in bioresearch
- ✓ Easy to administer and to use

# Questions?

# Thank you!