

# ErbaExpert

Interface of ErbaExpert information system  
and laboratory information systems (LIS)



## Interface of ErbaExpert information system and laboratory information systems (LIS)

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Information given in this manual are necessary for proper instrument operation. Therefore, pay attention to this manual.

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## 1. Interface between ErbaExpert and LIS

### 1.1 Interface between ErbaExpert and Laboratory information systems (LIS)

This material describes the relationship between the ErbaExpert information system and laboratory information systems.

**Before using the software, please read the entire manual. Save the manual so that users can access it whenever it is needed.**

### 1.2 Symbols and signs

These symbols provide you with basic information and warn you of possible danger.



In vitro diagnostics device



Warning: biological alert



Warning: the risk of harming your health or your immediate surroundings



Producer



Production date



Separate collection of electrical and electronic equipment

## 1.3 Software application area

ErbaExpert is an expert microbiological software that allows the interpretation and expert analysis of microbiological samples in accordance with the EUCAST and CLSI international standards.

The software may only be operated by personnel/staff trained in its use.

The software may only be used in accordance with the designated area of use.



**Warning: If the user uses a device in other than the producer defined way, the protection afforded by the device may be compromised/ The protection provided by the device may be impaired/ disrupted.**

The software was designed according to the EU directives.

## 1.4 CE marking



Based on the directions listed below and the information in the manual, the product is CE marked.

### 1.4.1 Directive 98/79 / EC on In Vitro Diagnostic Medical Devices

A risk management analysis for this software has been performed. This analysis is part of the ISO documentation of the company and CE software documentation.

## 2. Introduction

This material describes the relationship between the ErbaExpert information system and laboratory information systems. The solution described is based on the creation of a simple XML-based interface between these information systems. The proposed interface will allow batch data transmission between these information systems with minimal overhead as much as possible.

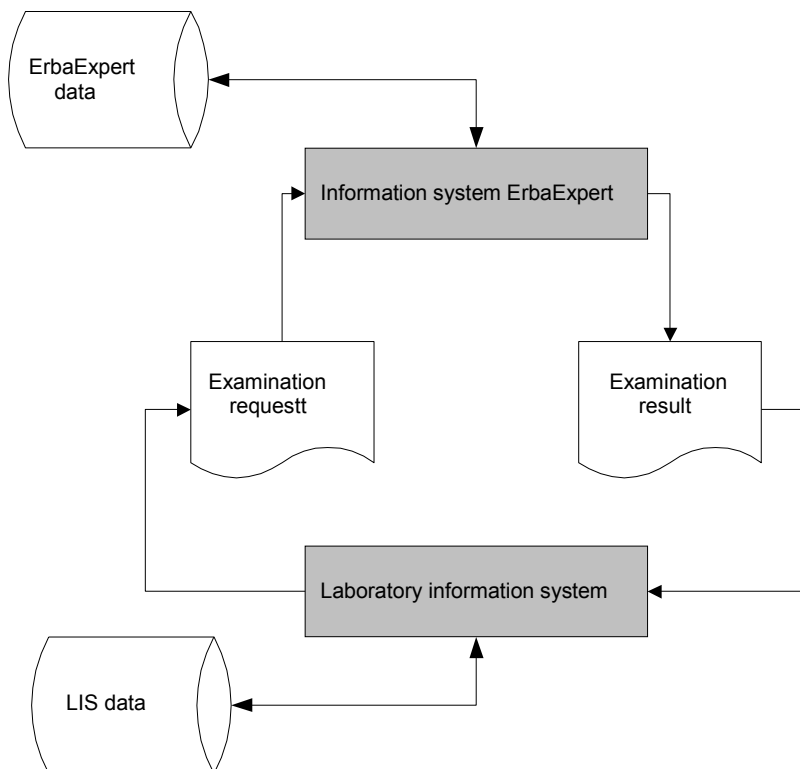


Figure 1 – Interface overview

### 3. Characteristics of the solution

An interface is created to perform the tests to ensure the necessary functionality and exchange of information between the ErbaExpert information system and laboratory information systems.

From a time point of view, this is batch data processing without the need for an immediate response (off-line process). The response to the request is not generated in the ErbaExpert system as soon as the request is received.

Data exchanged between laboratory information systems and the ErbaExpert system is passed in XML message format. Messaging in this version of the interface is performed using the local LAN.

The examinations themselves are carried out in such a way that the system requesting the examination sends a request for the examination to the ErbaExpert system together with the data necessary for the examination. Upon receipt of a request in the ErbaExpert system, the interactive processing of the sent data is performed, and the response is returned, containing the result (XML file with the result of the examination).

## 4. Technical solution

### 4.1 Document conventions

To highlight rules for using XML constructs, conventions are used in this document:

- The XML element names are enclosed in broken brackets using `<Arial>` font in brown colour
- The XML attributes names are written using `arial` font in brown colour

### 4.2 Using of XML schemas

On the ErbaExpert side of the interface, there are schemas of all the messages associated with the interface in the W3C XML Schema format. Schemas can be used to validate input and output message documents.

The system defines its own data types, especially for lists of allowed values and for data subject to internal formatting. Definitions of custom data types are not included directly into specific message schemas, but are stored externally in the data type schema and in list schemas, and are referenced in the message schemas in the standard way.

The schemas are divided into two levels. At the basic level there is a schema supporting common data types for all types of messages, along with the ErbaExpert enumeration list schemas. Above them, schemas are created for specific interface input and output messages. The schema with the basic data types of the ErbaExpert interface is given in Appendix 14 to this document; list schemas are directly linked to the ErbaExpert system and are always generated when the corresponding list is changed in the system.

All schemas are physically located in the XML\Schemas\CommSrv directory of the ErbaExpert root directory (see Figure 2).

### 4.3 Code page of documents used

The code page of all transmitted messages must conform to the UTF-8 standard required in the XML specification.



## 4.4 Date and time format

Date and time format data is used in accordance with data type `xsd:date` of XML Schema specification dated May 2, 2001 (yyyy-mm-dd format). This is the data in the `requestDate` attribute in the root element of the transmitted messages and `responseDate` in the root of the output message.

## 4.5 Message model

The simple XML message model is used for the proposed interface. All the data needed to process the message is carried inside the message. No wrapping protocols are used in this version.

## 4.6 Message transmission

Local LANs are used to send messages. The ErbaExpert root directory contains a shared directory structure supporting bidirectional message flow (see Figure 2).

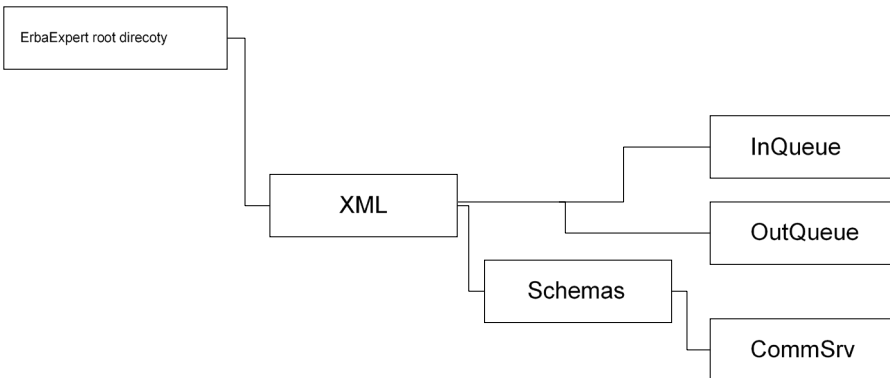


Fig. 2 – Directory structure needed for reporting

## 4.7 Message processing application logic

An application (LIS) requesting an exam passes a request message to the **InQueue** directory. This directory is used as the ErbaExpert messaging entry queue.

The naming of message files does not have to follow any logic. Only an .xml file extension is required. The file name can either be generated randomly, or any logic determined by the sending application.

The message root element attributes section (**requestDate** attributes for the request date definition, **batchID** to identify the batch of a unique ID) is used to define the input parameter parameters. In the same way, a section of the response element root elements (**responseDate**, **batchID** attributes) is created.

The ErbaExpert system removes this message from the incoming queue after it has successfully retrieved the message. This is followed by a time-separated interactive message processing. The ErbaExpert system generates an output message after scanning, and inserts it into the **OutQueue** directory that serves as the message queue. The naming of output report files is governed by identical rules as for input messages.

An application requesting an examination feeds a message queue in the **OutQueue** directory. The resolution of whether a correct answer, an error message, or an informative set-change message is possible from the content of the message - it is advisable to make decisions using root message elements.

Using client-side validation parser is not required when sending messages, but it is strongly recommended. On the ErbaExpert service side, validation is required.

### 4.7.1 Examination request message

The request message contains the following information:

- The root element of this message is **<RequestList>** element.
- The mandatory **requestDate** attribute bears the date of the request.
- The mandatory **batchID** attribute contains unambiguous batch identification. This must be unique throughout the messaging history. An attempt to reassign the value of this attribute causes a processing error.
- The **<IsolateExamination>** element contains data on a single identified strain. It contains:
  - o Parent Element **<IsolateExamination>**
  - o Mandatory element **<IsolateCode>** containing the strain label in the sending information system
  - o The optional **<LabCode>** element contains a station code that performs the required analysis. It is inserted when the ErbaExpert system supports separate processing of isolates at individual stations.
  - o The optional **<MaterialCode>** element contains material code. Specifying the material type allows you to refine the results of the sensitivity determination.
  - o The optional **<SystemicIndicator>** element contains systemic infection indicator. Specifying it allows you to refine the results of the sensitivity determination
  - o The optional **<TestList>** element is the wrapping element of the list of required methods. Contains **<MethodCode>** elements that identify the required examination methods.
  - o The optional **<TaxonCode>** element contains the result of the strain identification already performed (e.g. by the MALDI method).

The XML schema of the examination request message is given in Annex 1, the model document of this message in Annex 2.

#### 4.7.2 Examination result message

The response message contains the following information:

- The root element of this message is **<ResultList>**.
- The mandatory **responseDate** attribute carries the examination date (response batch creation).
- The mandatory **batchID** attribute contains unambiguous batch identification. This value is not taken from the request message; since the isolate set in the input and output message may vary, it only serves to uniquely identify the message.
- The mandatory **<Isolate>** element contains data on the individual isolate being processed. It contains:
  - o Mandatory element **<IsolateCode>** with unique isolate identifier.
  - o The optional **<IdentificationMethodList>** element contains a list of the identities made for this isolate.
  - o Mandatory element **<Method>** contains the result of the examination for one identification method.
  - o The mandatory **<Code>** element contains the method identifier.
  - o Mandatory element **<TaxonCode>** contains the resulting identification tax code.
  - o Mandatory element **<QualityCode>** contains the identification result quality code. It must contain a value from the list in the ErbaExpert data type schema.
  - o Optional element **<AtbMethodList>** contains a list of sensitivity tests performed for this isolate.
  - o Mandatory element **<Method>** contains the result of an examination for one sensitivity determination method.
  - o The mandatory **<Code>** element contains the method identifier.
  - o Mandatory **<AtbList>** contains a list of the investigated antibiotics.
  - o Mandatory **<Atb>** contains an examination result for one antibiotic
  - o Mandatory **<AtbCode>** contains an antibiotic identifier
  - o Mandatory element (for disc diffusion method) **<ZoneDiameter>** contains the diameter of the disc diffusion method inhibition zone.
  - o Mandatory element (for the MIC method) **<MicValue>** contains the minimum inhibitory concentration of the given antibiotic.
  - o Optional element **<SusceptibilityCode>** contains the sensitivity code of the given strain to the given antibiotic.
  - o Optional element **<ExpertMessage>** contains a list of expert messages for the isolate.
  - o Optional element **<DoseMessage>** contains a list of recommended ATB dosages for a given isolate.
  - o Optional element **<EvaluateMessage>** contains a list of reports for the isolate that are intended for the end user (physician).
  - o Optional element **<SummaryMessage>** contains a list of reports for the isolate, completed by the system user, which are intended for the end user (physician).
  - o Optional element **<SimpleMessageList>** contains particular messages for a given isolate with identification of their type.

The XML schema of the examination response message is given in Annex 3, the model document of this message in Annex 4.

### 4.7.3 Errors processing

If an error occurs at the message level when processing the input message (no required information can be returned), an error message is generated.

The error message has the following structure:

- The root element of this message is **<CommunicationErrorList>**.
- The mandatory **errorDate** attribute carries the date when the message was created.
- The **<Error>** element contains error data.
  - o Mandatory element **<FileName>** contains the full name of the batch file with the requirement for examination.
  - o The optional **<batchID>** element contains a unique batch ID. This is taken from an input request message and serves to uniquely assign a query and an error response. If the input message could not be processed, it is missing.
  - o The mandatory element **<ErrorType>** identifies the general type of error. It must contain a value from the list of general types of errors in the ErbaExpert data type schema.
  - o Mandatory element **<ErrorCode>** identifies a specific type of error. It must contain a value from the list of specific types of errors in the ErbaExpert data type schema.
  - o The optional **<ErrorText>** contains a text description of the error.

The codes for possible specific errors presented below are listed in the ErbaExpert interface schema:

- a) Client** – indicates the occurrence of client errors, e.g. the document does not match the schema, the syntactic error of the document, etc.
- b) Server** – indicates ErbaExpert service errors
- c) Client.Validity** – document validation error
- d) Client.NonXML** – the passed document is not an XML file
- e) Client.WellFormedness** – a failure to verify the correct document structure
- f) Client.RepeatedMessage** – attempt to resend a message with the same document **batchID**
- g) Server.Program** – ErbaExpert service internal error
- h) Server.Service** – general service error - other errors outside of **g)**

The **Client** and **Server** error classes mean generic error classes. They usually do not appear separately and are used with extension; however, they do not prevent their use in indicated cases.

The XML schema of the error message is given in Annex 5, the model document of this message in Annex 6.

## 5. Work with ErbaExpert system

This chapter describes the specific steps the ErbaExpert user must perform if he plans to use the ErbaExpert service to communicate with laboratory identification systems.

### 5.1 Setting of ErbaExpert

ErbaExpert settings for working with LIS must be done with the rights of the system administrator. The settings are described in detail in Chapter **7.5 – LIS Communication** of the ErbaExpert administrator manual.

### 5.2 Working in XML communication mode with LIS

A description of the LIS communication mode is contained in Chapter **6.5 - Import data of isolates from LIS, assigning of respective examinations, export data to LIS**, and Chapter **6.6 - Import of examination requests from LIS, results export to LIS** of the ErbaExpert user manual.

## 6. References

### 6.1 Normative references

Normative references provide references to the standards used to define and design the interface between the ErbaExpert system and laboratory information systems.

#### XML

Extensible Markup Language (XML) 1.0 (Second Edition). *W3C Recommendation 6 October 2000*. See <http://www.w3.org/TR/REC-xml>

#### XML Namespaces

Namespaces in XML. *World Wide Web Consortium 14-January-1999*. See <http://www.w3.org/TR/REC-xml-names>

#### XML Schema

XML Schema Part 0: Primer. *W3C Recommendation, 2 May 2001*. See <http://www.w3.org/TR/xmlschema-0/>

## 7. Changes versus version 1.00

No	Change description
1	Adding of <MaterialCode> and <SystemicIndicator> elements to Request message
2	Adding of <ExpertMessage>, <DoseMessage> and <EvaluateMessage> to Result message
3	Adding of <SummaryMessage> and <SimpleMessageList> elements to Result message

## 8. Annexes

### 8.1 Annex No.1 Request message XML schema of the ErbaExpert system

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- edited with XMLSpy v2013 rel. 2 sp2 (x64) (http://www.altova.com) by Jan Kotrle (ASD Software, s.r.o.) -->
<xs:schema xmlns="urn:cz:ErbaLachema:schemas:ErbaExpert:IsolateRequest:v1" xmlns:xs="
http://www.w3.org/2001/XMLSchema" xmlns:dt="urn:cz:ErbaLachema:schemas:ErbaExpert:datatypes:v1"
targetNamespace="urn:cz:ErbaLachema:schemas:ErbaExpert:IsolateRequest:v1" elementFormDefault="qualified">
  <xs:import namespace="urn:cz:ErbaLachema:schemas:ErbaExpert:datatypes:v1" schemaLocation="
ErbaExpertTypes.xsd"/>
  <xs:element name="RequestList">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="IsolateExamination" maxOccurs="unbounded">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="IsolateCode" type="dt:IsolateCodeType"/>
              <xs:element name="LabCode" type="dt:LabCodeType" minOccurs="0"/>
              <xs:element name="Pacient" type="dt:PacientStructure" minOccurs="0"/>
              <xs:element name="DiagnosisCode" type="dt:DiagnosisCodeType" minOccurs="0"/>
              <xs:element name="MaterialCode" type="dt:MaterialCodeType" minOccurs="0"/>
              <xs:element name="SystemicIndicator" type="dt:SystemicIndicatorType" minOccurs="0"/>
              <xs:element name="Sample" type="dt:SampleStructure" minOccurs="0"/>
              <xs:element name="TestList" minOccurs="0">
                <xs:complexType>
                  <xs:sequence>
                    <xs:element name="MethodCode" type="dt:MethodCodeType" maxOccurs="unbounded"/>
                  </xs:sequence>
                </xs:complexType>
              </xs:element>
              <xs:element name="TaxonCode" type="dt:TaxonCodeType" minOccurs="0"/>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
      </xs:sequence>
      <xs:attribute name="requestDate" type="xs:date" use="required"/>
      <xs:attribute name="batchID" type="dt:batchIDType" use="required"/>
    </xs:complexType>
    <xs:unique name="IsolateCode">
      <xs:selector xpath="IsolateExamination"/>
      <xs:field xpath="IsolateCode"/>
    </xs:unique>
  </xs:element>
</xs:schema>
```

### 8.2 Annex No.2 Model request message of the ErbaExpert system

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Sample XML file generated by XMLSpy v2013 rel. 2 sp2 (x64) (http://www.altova.com) -->
<RequestList requestDate="1967-08-13" batchID="a" xsi:schemaLocation="
urn:cz:ErbaLachema:schemas:ErbaExpert:IsolateRequest:v1 ee_isolate_request.xsd" xmlns="
urn:cz:ErbaLachema:schemas:ErbaExpert:IsolateRequest:v1" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:dt="urn:cz:ErbaLachema:schemas:ErbaExpert:datatypes:v1">
  <IsolateExamination>
    <IsolateCode>23-6</IsolateCode>
    <MaterialCode>BL</MaterialCode>
    <SystemicIndicator>true</SystemicIndicator>
    <TestList>
      <MethodCode>60</MethodCode>
      <MethodCode>10</MethodCode>
    </TestList>
    <TaxonCode>LOPRO</TaxonCode>
  </IsolateExamination>
</RequestList>
```



## 8.3 Annex No.3 Response message XML schema of the ErbaExpert system

```
<?xml version="1.0" encoding="UTF-8"?>
<xs:schema xmlns="urn:cz:Diagnosics:schemas:IDAST:IsolateResult.v1" xmlns:xs="http://www.w3.org/2001/XMLSchema"
  xmlns:dtt="urn:cz:Diagnosics:schemas:IDAST:datatypes.v1" targetNamespace="urn:cz:Diagnosics:schemas:IDAST:IsolateResult.v1" elementFormDefault="qualified">
  <xs:import namespace="urn:cz:Diagnosics:schemas:IDAST:datatypes.v1" schemaLocation="IDASTTypes.xsd"/>
  <xs:element name="ResultList">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="Isolate" maxOccurs="unbounded">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="IsolateCode" type="dtt:IsolateCodeType"/>
              <xs:element name="IdentificationMethodList" minOccurs="0">
                <xs:complexType>
                  <xs:sequence>
                    <xs:element name="Method" maxOccurs="unbounded">
                      <xs:complexType>
                        <xs:sequence>
                          <xs:element name="Code" type="dtt:MethodCodeType"/>
                          <xs:element name="TaxonCode" type="dtt:TaxonCodeType"/>
                          <xs:element name="QualityCode" type="dtt:IdentificationQualityCodeType" minOccurs="0"/>
                          <xs:element name="FtypeCode" type="dtt:FtypeCodeType" minOccurs="0"/>
                        </xs:sequence>
                      </xs:complexType>
                    </xs:element>
                  </xs:sequence>
                </xs:complexType>
              </xs:element>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="AtbMethodList" minOccurs="0">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="Method" maxOccurs="unbounded">
                <xs:complexType>
                  <xs:sequence>
                    <xs:element name="Code" type="dtt:MethodCodeType"/>
                    <xs:element name="AtbList">
                      <xs:complexType>
                        <xs:sequence>
                          <xs:element name="Atb" maxOccurs="unbounded">
                            <xs:complexType>
                              <xs:sequence>
                                <xs:element name="AtbCode" type="dtt:AtbCodeType"/>
                                <xs:choice minOccurs="0">
                                  <xs:element name="ZoneDiameter" type="dtt:InhibitionZoneDiameterType"/>
                                  <xs:element name="MicValue" type="dtt:MicValueType"/>
                                </xs:choice>
                                <xs:element name="SusceptibilityCode" type="dtt:SusceptibilityCodeType" minOccurs="0"/>
                              </xs:sequence>
                            </xs:complexType>
                          </xs:element>
                        </xs:sequence>
                      </xs:complexType>
                    </xs:element>
                  </xs:sequence>
                </xs:complexType>
              </xs:element>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:element name="ExpertMessage" type="dtt:MessageType" minOccurs="0"/>
        <xs:element name="DoseMessage" type="dtt:MessageType" minOccurs="0"/>
        <xs:element name="EvaluationMessage" type="dtt:MessageType" minOccurs="0"/>
        <xs:element name="SummaryMessage" type="dtt:MessageType" minOccurs="0"/>
        <xs:element name="SimpleMessageList" minOccurs="0">
          <xs:complexType>
            <xs:sequence>
              <xs:element name="Message" maxOccurs="unbounded">
                <xs:complexType>
                  <xs:sequence>
                    <xs:element name="MessageClassID" type="dtt:MessageClassType"/>
                    <xs:element name="MessageText" type="dtt:MessageType"/>
                  </xs:sequence>
                </xs:complexType>
              </xs:element>
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        <xs:attribute name="responseDate" type="xs:date" use="required"/>
        <xs:attribute name="batchID" type="dtt:batchIDType" use="required"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
</xs:schema>
```

## 8.4 Annex No.4 Model response message of the ErbaExpert system

```

<?xml version="1.0" encoding="UTF-8"?>
<ResultList responseDate="2017-06-10" batchID="res11"
xsi:schemaLocation="urn:cz:ErbaLachema:schemas:ErbaExpert:IsolateResult:v1 EE_isolate_result.xsd"
xmlns="urn:cz:ErbaLachema:schemas:ErbaExpert:IsolateResult:v1" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <Isolate>
    <IsolateCode>23-6</IsolateCode>
    <IdentificationMethodList>
      <Method>
        <Code>12</Code>
        <TaxonCode>CESPP</TaxonCode>
        <QualityCode>4</QualityCode>
      </Method>
    </IdentificationMethodList>
    <AtbMethodList>
      <Method>
        <Code>23</Code>
        <AtbList>
          <Atb>
            <AtbCode>AMP</AtbCode>
            <ZoneDiameter>25</ZoneDiameter>
            <SusceptibilityCode>S</SusceptibilityCode>
          </Atb>
          <Atb>
            <AtbCode>AZT</AtbCode>
            <ZoneDiameter>25</ZoneDiameter>
            <SusceptibilityCode>S</SusceptibilityCode>
          </Atb>
          <Atb>
            <AtbCode>CLI</AtbCode>
            <ZoneDiameter>21</ZoneDiameter>
            <SusceptibilityCode>S</SusceptibilityCode>
          </Atb>
          <Atb>
            <AtbCode>FET</AtbCode>
            <ZoneDiameter>10</ZoneDiameter>
            <SusceptibilityCode>R</SusceptibilityCode>
          </Atb>
        </AtbList>
      </Method>
    </AtbMethodList>
    <Method>
      <Code>89</Code>
      <AtbList>
        <Atb>
          <AtbCode>DOR</AtbCode>
          <MicValue>16</MicValue>
        </Atb>
        <Atb>
          <AtbCode>GRX</AtbCode>
          <MicValue>0.25</MicValue>
        </Atb>
        <Atb>
          <AtbCode>SCF</AtbCode>
          <MicValue>0.5</MicValue>
        </Atb>
      </AtbList>
    </Method>
  </AtbMethodList>
</Isolate>
</ResultList>

```

## 8.5 Annex No.5 Error message XML schema of the ErbaExpert system

```
<?xml version="1.0" encoding="UTF-8"?>
<xs:schema xmlns="urn:cz:ErbaLachema:schemas:ErbaExpert:error:v1"
xmlns:xs="http://www.w3.org/2001/XMLSchema" xmlns:dt="urn:cz:ErbaLachema:schemas:ErbaExpert:datatypes:v1"
targetNamespace="urn:cz:ErbaLachema:schemas:ErbaExpert:error:v1" elementFormDefault="qualified"
attributeFormDefault="unqualified">
  <xs:import namespace="urn:cz:ErbaLachema:schemas:ErbaExpert:datatypes:v1"
schemaLocation="ErbaExpertTypes.xsd"/>
  <xs:complexType name="ErrorStructure">
    <xs:sequence>
      <xs:element name="FileName" type="xs:string"/>
      <xs:element ref="batchID" minOccurs="0"/>
      <xs:element name="ErrorType" type="dt:ErrorType"/>
      <xs:element name="ErrorCode" type="dt:ErrorCodeType"/>
      <xs:element name="ErrorText" type="xs:string"/>
    </xs:sequence>
  </xs:complexType>
  <xs:element name="batchID" type="dt:batchIDType"/>
  <xs:element name="CommunicationErrorList">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="Error" type="ErrorStructure" maxOccurs="unbounded"/>
      </xs:sequence>
      <xs:attribute name="errorDate" type="xs:date" use="required"/>
    </xs:complexType>
  </xs:element>
</xs:schema>
```

## 8.6 Annex No.6 Model error message of the ErbaExpert system

```
<?xml version="1.0" encoding="UTF-8"?>
<CommunicationErrorList errorDate="2017-06-10"
xsi:schemaLocation="urn:cz:ErbaLachema:schemas:ErbaExpert:error:v1 EE_error.xsd"
xmlns="urn:cz:ErbaLachema:schemas:ErbaExpert:error:v1" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <Error>
    <FileName>IMP21.XML</FileName>
    <batchID>req21</batchID>
    <ErrorType>local</ErrorType>
    <ErrorCode>Client</ErrorCode>
    <ErrorText>Duplicitní kód izolátu - 44/8</ErrorText>
  </Error>
</CommunicationErrorList>
```



**Erba Lachema s.r.o.**

Karásek 2219/1d, 621 00 Brno, Česká republika

Tel.: +420 517 077 111

E-mail: [diagnostics@erbamannheim.com](mailto:diagnostics@erbamannheim.com)

[www.erbalachema.com](http://www.erbalachema.com)