



# An overview of the latest version of the German RiliBÄK

**Matthias Nauck**

**Institut of Clinical Chemistry and Laboratory Medicine  
Ernst-Moritz-Arndt-University, Greifswald**



# Prospective RiliBÄK



Gorch Fock

# Prospective RiliBÄK

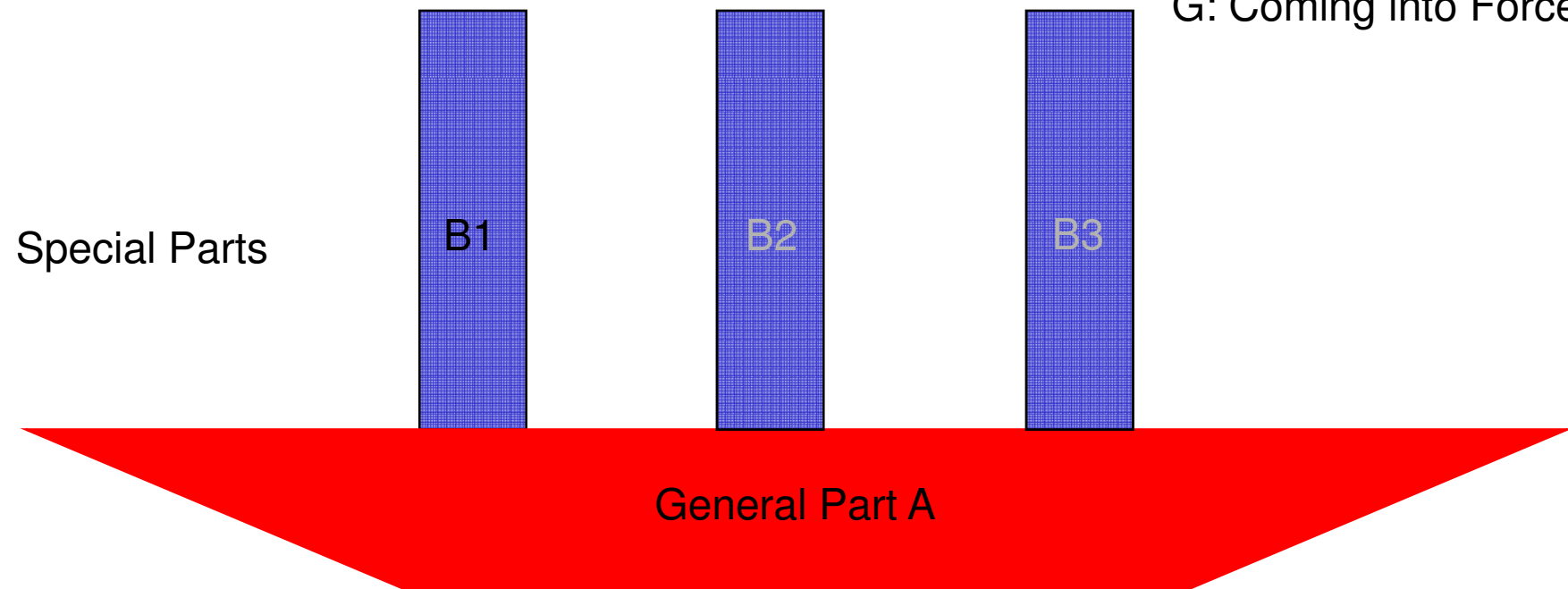
C: Advisory Board

D: Expert Groups

E: Round robin tests

F: Provisional Rules

G: Coming into Force



# General Part A:

## Fundamental Requirements for Quality Assurance of Medical Laboratory Examinations

### 1. **Scope**

- This guideline provides rules for the quality assurance of medical laboratory examinations as a part of medical care

### 2. **Objective**

- The guideline is aimed at safeguarding the quality of analyses carried out in medical laboratories to protect the patients
  - Preamanalytical period (DIN EN ISO 15189)
  - Medical laboratory test procedures
  - Post analytical phase

### 3. **Terminology**

# General Part A:

## Elements of the Quality Management

### **4. Structure**

- Identification (legally identifiable)
- Organisation (Responsibilities and duties clearly defined)

### **5. Resources**

- Management (professionally qualified)
- Personnel (continued education, training of new employees)
- Accomodation and environmental conditions (lab space, storage space)
- Equipment (necessary to fulfill its functions)

# General Part A:

## Elements of the Quality Management

### **6. Medical laboratory Examinations**

#### **1. Preanalytical period**

##### **5. sample collection document**

1. Preparation of the patient
2. Completion of request form or electronic request
3. Required patient information
4. type and quantity of specimen to be collected
5. any special timing information with regard to collection, storage and transportation of the specimen, if required
6. sample collection including description of specimen container and any additives required
7. unique labeling of the specimen
8. any special sampling handling instructions regarding the time between collection and receipt at the laboratory
9. time limits for requesting additional analyses

# General Part A:

## Elements of the Quality Management

### 6. Medical laboratory Examinations

#### 2. Medical laboratory test procedures

1. The medical laboratory must only use procedures, which meet the **medical requirements**.
2. The medical laboratory must only use **validated procedures**. The procedure used for validation and the results thereof must be documented.

Comment: The validation has not be performed inside the specific laboratory. It is sufficient, to apply validated methods.

# General Part A:

## Elements of the Quality Management

### 6. Medical laboratory Examinations

#### 3. Post analytical phase

1. Results must be **technically validated** and **medically validated** taking into account the clinical data available.
2. **Procedures** must be in place, which define the **release** of results.
3. **Reports** must be clearly legible and must contain several data:

date, unique identification of the patient, name of medical laboratory, date and time of receipt of the specimen. ...



# General Part A:

## Elements of the Quality Management

### **7. Quality management system**

1. Quality management manual
2. Document control
3. Resolution of complaints
4. Examinations by referral laboratories
5. Nonconformities

### **8. Quality Assurance**

1. Internal quality assurance → see part B
2. External quality assurance → see part B

# Special Part B1:

## Quantitative tests in medical laboratories

### 1. Principles of quality assurance

1. **Minimum requirements** are listed that need to be met to assess the quality of quantitative results of examinations in medical laboratories.

2. **All** quantitative tests performed by medical laboratories are subject to **internal quality assurance** procedures.

3. All measurands listed in table B1 a to c are subject to **external quality assurance** procedures.

# Special Part B1:

## 2. Carrying out quality assurance




### 1. Internal quality assurance

1. Carrying out individual measurements of control samples
2. Evaluating the results of the individual measurements of control samples
3. Calculating and evaluating the **root mean square of the error of measurement** after completing a control cycle.
4. Establishing internal laboratory limits of permissible error for measurands that are not listed in Table B1
5. Point-of-care testing with unit-use reagents
6. Measurands with small test frequencies
7. Documentation

### 2. External quality assurance (round robin test)

What is the meaning of:  
root mean square of the error  
of measurement?

# Measurement uncertainty

Fehlertyp		zufällige Fehler	systematische Fehler	grobe Fehler
				falsche Scheibe benutzt
Präzision	optimal	schlecht	gut	—
Richtigkeit	optimal	gut	schlecht	—

poor

precision accuracy

# Total Error

Column 5 (RiliBÄK vom 24.8.2001):

- Random error of measurement: CV (%)

Column 6 (RiliBÄK vom 24.8.2001):

- Systematic error of measurement: bias (%)

Column 7 (RiliBÄK vom 24.8.2001):

- Total error (TE):

$$TE (\%) = 2 \times CV (\%) + \text{bias} (\%)$$

# RiliBÄK (24.8.2001): Table 1

Col. 5    Col. 6    Col. 7

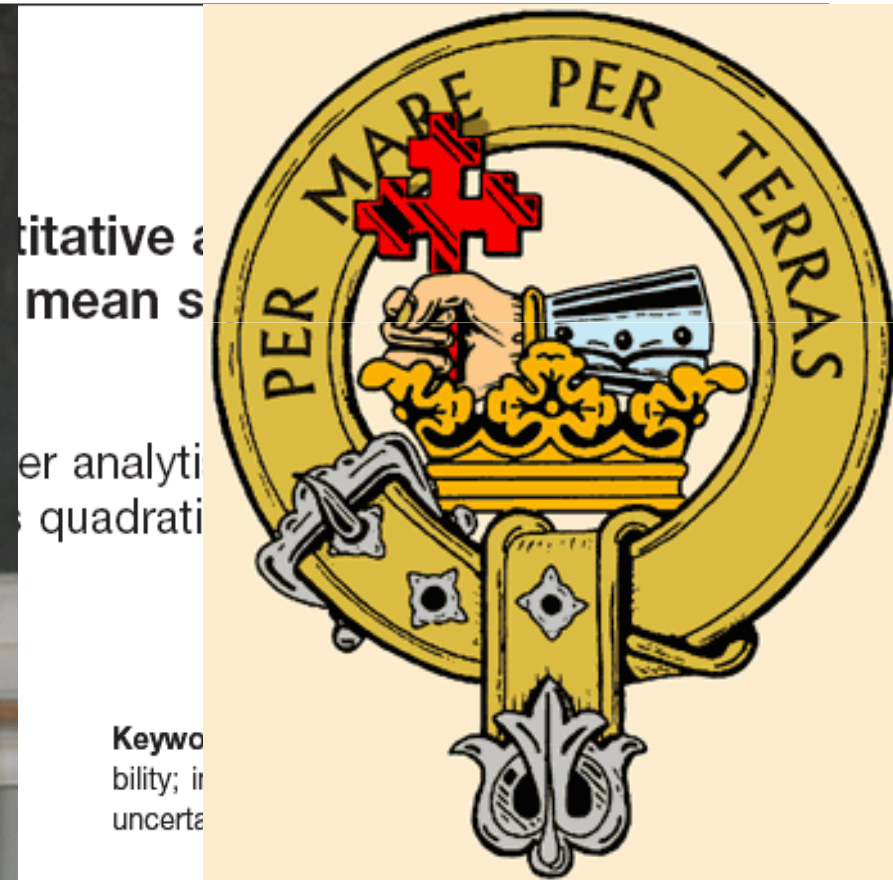
Analyt in Serum/Plasma	$\frac{\varepsilon_s}{\bar{x}}$	$\frac{\varepsilon_\delta}{x_r}$	$2 \frac{\varepsilon_s}{\bar{x}} + \frac{\varepsilon_\delta}{x_r}$
<b>Albumin</b>	<b>6%</b>	<b>11%</b>	<b>23%</b>
<b>Alpha-fetoprotein</b>	<b>10%</b>	<b>14%</b>	<b>34%</b>
<b>Bilirubin</b>	<b>7%</b>	<b>12%</b>	<b>26%</b>
<b>Calcium</b>	<b>3%</b>	<b>5%</b>	<b>11%</b>
<b>Cholesterol</b>	<b>4%</b>	<b>6%</b>	<b>14%</b>
<b>Glucose</b>	<b>5%</b>	<b>6%</b>	<b>16%</b>
<b>hCG</b>	<b>12%</b>	<b>14%</b>	<b>38%</b>
<b>Hemoglobin</b>	<b>2%</b>	<b>2%</b>	<b>6%</b>
<b>Lactat-Dehydrogenase</b>	<b>5%</b>	<b>8%</b>	<b>18%</b>
<b>Natrium</b>	<b>1,8%</b>	<b>2,5%</b>	<b>6,1%</b>

# Root mean square of the error of measurement

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Prof. Dr. rer. nat. Rainer Macdonald



family crest



# Root mean square of the error of measurement

$$\Delta = \sqrt{\frac{1}{n} \sum_{i=1}^n (x_i - x_r)^2}$$

because  $\sum_{i=1}^n (x_i - x_r)^2 = \sum_{i=1}^n (x_i - \bar{x})^2 + n(\bar{x} - x_r)^2$

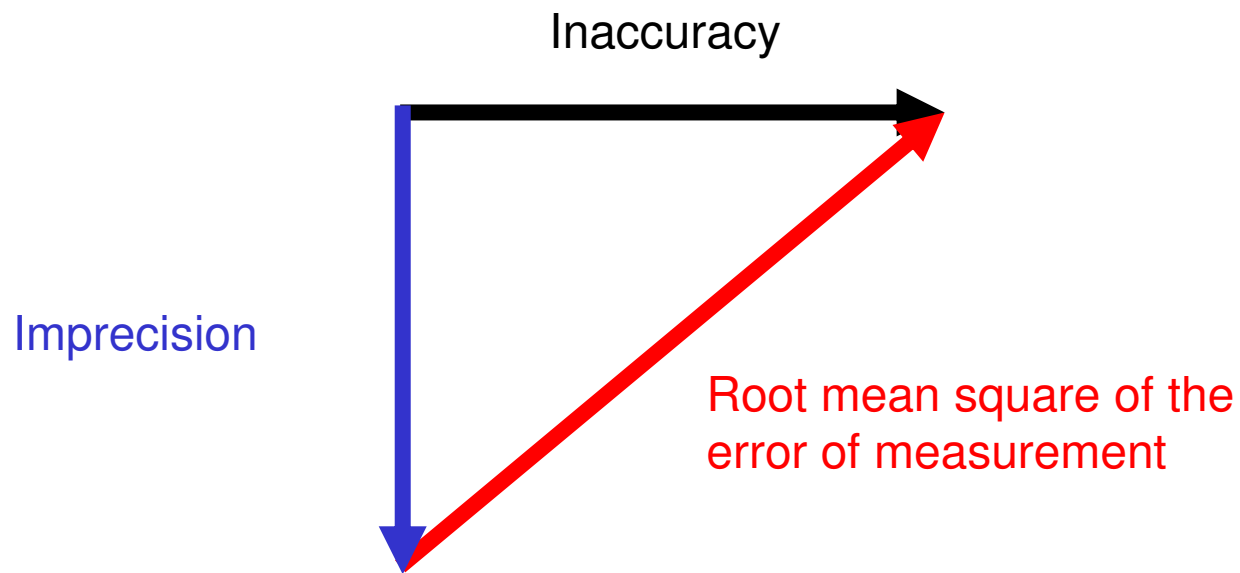
$$\Rightarrow \Delta = \sqrt{\frac{n-1}{n} s^2 + \delta^2}$$

↪ limit

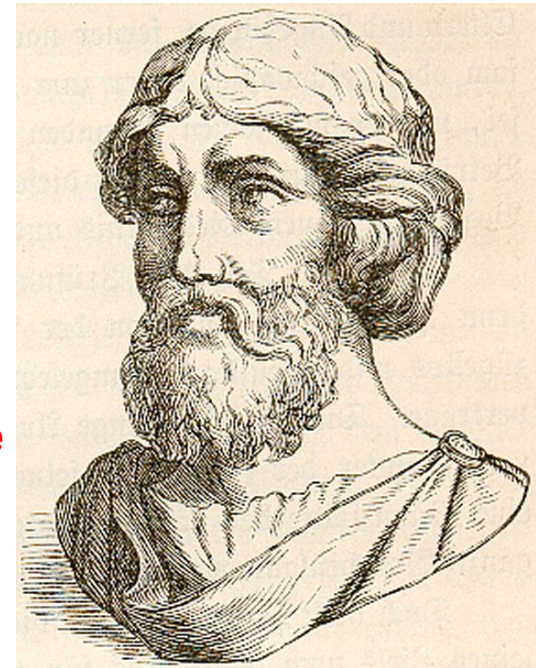
$$\Delta \leq \varepsilon_{\Delta} = \sqrt{\frac{n-1}{n} \varepsilon_s^2 + \varepsilon_{\delta}^2}$$

# principle:

## root mean square of the error of measurement



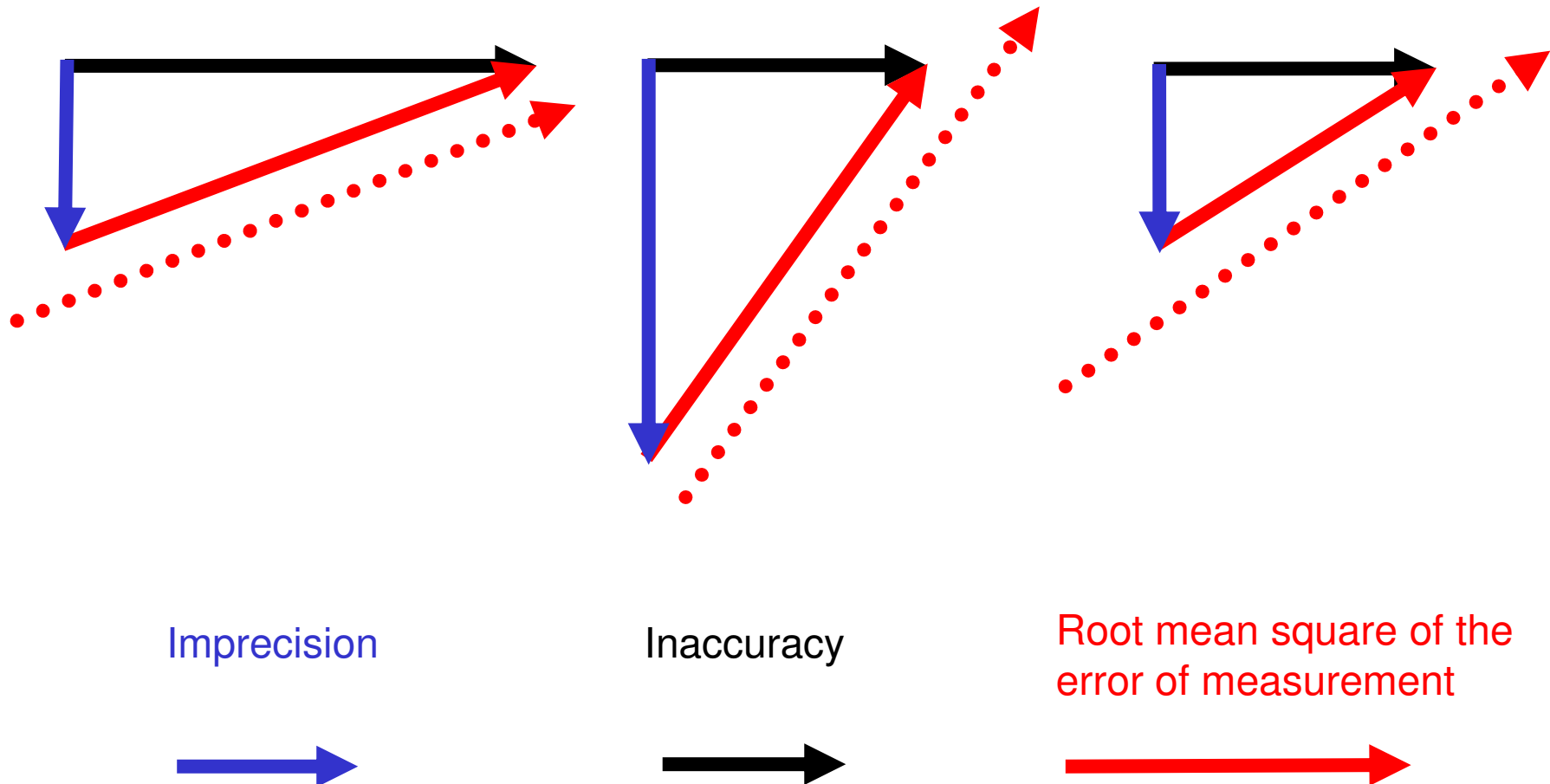
$$a^2 + b^2 = c^2$$



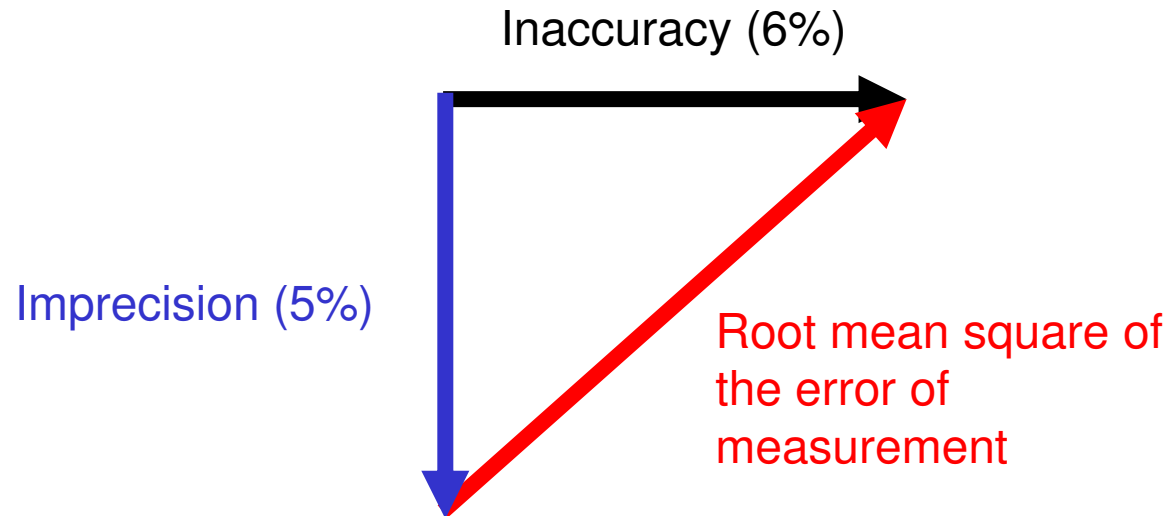
Pythagoras von Samos  
(570 v. Chr. – 510 v. Chr.)

principle:

root mean square of the error of measurement



# error limits



old RiliBÄK

Total error:

$$2 \times 5\% + 6\% = 16\%$$

New RiliBÄK

Root mean square of the error of measurement:

$$\sqrt{5^2 + 6^2} = 7.8\%$$

# Old and new RiliBÄK: Table 1

	Col. 5	Col. 6	Col. 7	new
Analyt in Serum/Plasma	$\frac{\varepsilon_s}{\bar{x}}$	$\frac{\varepsilon_\delta}{x_r}$	$2 \frac{\varepsilon_s}{\bar{x}} + \frac{\varepsilon_\delta}{x_r}$	$\frac{\sqrt{\frac{n-1}{n} \varepsilon_s^2 + \varepsilon_\delta^2}}{x_r}$
<b>Albumin</b>	<b>6%</b>	<b>11%</b>	<b>23%</b>	<b>12.4%</b>
<b>Alpha-fetoprotein</b>	<b>10%</b>	<b>14%</b>	<b>34%</b>	<b>17.0%</b>
<b>Bilirubin</b>	<b>7%</b>	<b>12%</b>	<b>26%</b>	<b>13.8%</b>
<b>Calcium</b>	<b>3%</b>	<b>5%</b>	<b>11%</b>	<b>5.8%</b>
<b>Cholesterol</b>	<b>4%</b>	<b>6%</b>	<b>14%</b>	<b>7.1%</b>
<b>Glucose</b>	<b>5%</b>	<b>6%</b>	<b>16%</b>	<b>7.8%</b>
<b>hCG</b>	<b>12%</b>	<b>14%</b>	<b>38%</b>	<b>18.1%</b>
<b>Hemoglobin</b>	<b>2%</b>	<b>2%</b>	<b>6%</b>	<b>2.8%</b>
<b>Lactat-Dehydrogenase</b>	<b>5%</b>	<b>8%</b>	<b>18%</b>	<b>9.3%</b>
<b>Natrium</b>	<b>1,8%</b>	<b>2,5%</b>	<b>6,1%</b>	<b>3.1%</b>

Assessment of the analytical quality by **only one relevant parameter**

## 2.2 External quality assurance

1. Taking part in **one** round robin test **per quarter** for each measurand listed in Table B1 a to c if the medical laboratory makes this test available
3. The obligation specified in paragraph 1 **does not apply to tests based on unit-use reagents** that are within the context of point-of-care-testing and that are carried out
  - a) in the doctor's office ...,
  - b) in hospitals where the central laboratory is responsible for carrying out internal quality assurance measures and determines the measurand itself.

# Summary

- Quality Management is a duty
  - Applying the **root mean square of the error of the measurement**, only one cut-off has to be taken into account
  - Calculation of the new **cut-offs** are based on **former specifications**
- previous experiences are transferable

The ride of the new RiliBÄK has started ...



Sagres II (sister ship of the Gorch Fock)





University- and Hansestadt Greifswald - Wieck