External Quality Assessment (EQA) for cfDNA in pregnancy

June 23, 2019
11.00 – 12.30
ISBT Basel
WP cfDNA subsection

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• **Sunday 23rd June** meeting for the cfDNA subsection-
  – Venue is Boston 3, Basel Convention Centre
  – Meeting time **11 to 12.30 am.**
Disclaimer & Disclosure

Disclaimer
• The views expressed do not necessarily represent the view of the National Institutes of Health, Department of Health and Human Services, or U.S. Federal Government.

Disclosure
• No conflicts of interest.

Off-Label Usage
• Assays for cfDNA are not FDA approved in the US.
Topics

• What INSTAND stands for.
  – 4 facts sheets

• What we are doing with EQA since the 2000s.
  – 2 slides

• What we are planning to do.
  – 2 statement slides and 1 picture of the evaluation documents

  – Keep it short: 2 – 4 slides per topic.
What **INSTAND e.V.** stands for

**Scientific society for promoting quality assurance**

**in medical laboratories e.V**

**INSTAND e. V.**

• is a **non-profit, interdisciplinary scientific medical society** and

• cooperates with a unique and large network of scientists,

• who are also serving as advisers and ring test leaders for External Quality Assessment schemes (EQA schemes = interlaboratory comparison = proficiency testing = ring trial = round robin test)

in all essential fields of laboratory medicine **since 1968**.

**INSTAND e.V.**

• Is accredited according to DIN/ISO17043 for reference institutions

The certificates are valid for laboratory accreditation processes.
Facts about INSTAND e.V.
Scientific society for promoting quality assurance in medical laboratories e.V.

The results of these EQA schemes
- are scientifically evaluated
- and are basis for surveilling the competence of medical diagnostic laboratories as well as the performance of \textit{in vitro} diagnostic medical devices.

The EQAs follow
- and the Guideline for Quality Assurance of Diagnostic Analyses in Medical Laboratories of the German Medical Association (Rili-BÄK).
INSTAND e.V. – A few more numbers

Development of EQA programs

Development of number of participants

cfDNA @ ISBT Basel 2019
Behnaz Bayat PhD
Univ Giessen, Germany
Facts about INSTAND e.V.
General EQA procedure

Registration

Shipment of Samples

Analysis in Lab

Reporting results

Publication of results

Expert evaluation

cfDNA @ ISBT Basel 2019
Behnaz Bayat PhD
Univ Giessen, Germany
What we are doing since the 2000s

• EQA for molecular immunohematology
• originated 1997 with INSTAND since fall 2006
• organization by Bein, Giessen & Flegel, Bethesda MD
• ~ 100 institutions participating worldwide Oldest and largest EQA available with comprehensive coverage of blood group, platelet and granulocyte antigens
Published since 2000

Transfusion Medicine, 2001, 11, 211–219

Workshop Report on the Genotyping of Blood Cell Alloantigens

H. Kroll, B. Carl, S. Santoso, J. Bux and G. Bein Institute for Clinical Immunology and Transfusion Medicine, Justus Liebig University Giessen, Germany

Received 20 June 2000; accepted for publication 4 January 2001

External quality assessment in molecular immunohematology: the INSTAND proficiency test program

Willy A. Flegel,1 Ion Chiosea,1 Ulrich J. Sachs,2 and Gregor Bein2
What we are planning to do.

• Establish an EQA for cfDNA in pregnancy
  – to be organized in collaboration by Flegel/Bein/Clausen

• For worldwide participation
  – logistics managed by INSTAND

• Affordable EQA fee
  – similar to established EQA since 2006, shipment at cost
Some proposed technical features.

- Real samples of cell free plasma from pregnant women
  - D neg mother with *RHD* gene positive fetus
  - pooled material and comparable control material
  - at least 2 samples per EQA shipment, possibly more.
- Initially planned for one EQA shipment per year.
  - in spring or autumn? Start immediately when logistics established?
- Online result submission
- Certificates in the mail
Samples sheets for Evaluation Documents, INSTAND style

Certificates

Evaluation and statistics