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CONNECTS HEALTH, SCIENCE AND SOCIETY

Molecular Biology and Cytometry (MB&C)
COURSE 2026
For all who work with molecular diagnostics, (flow)cytometry or microscopy techniques in a (clinical) laboratory

5 + 6 February 2026
University Colleges Leuven-Limburg (UCLL), Campus Gasthuisberg
www.ucll.be/MBC2026

UCLL RESEARCH & EXPERTISE
BSAC
Molecular Diagnostics be

External quality assessment (EQA) in Molecular Biology

A Belgian perspective

Joséphine Lantoine, PhD

6/02/2026

.be

Summary

1. All you need to know about (Sciensano's) EQA
2. The context of molecular biology EQA in Belgium
3. Assessing quality of genetic tests
4. Benefits for laboratories
5. Future goals

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Creativity

Thinking
out
of the box

Imagination

Think big

- To improve future results
- To correct past results where a significant impairment of results has been revealed
- Comparison of various analytical techniques
- To standardize your results with your peers
- To monitor laboratory performance over time
- To be confronted to challenging samples (eg. Infectious diseases)
- To evaluate the uniformity of the interpretation of the results (e.g Pathology)
- To develop and monitor staff competence

Buchta *et al.* Clin Chem Lab Med 2025; 63(5): 879–897

Process of comparing laboratory's test results to an **outside source**

- Samples sent by reference laboratory
- Samples exchanged between laboratories
- Samples sent by an external organisation namely **EQA provider**

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Quality of laboratories

BELAC 081-PT

https://www.sciensano.be/fr/qualite-des-laboratoires

https://www.sciensano.be/nl/kwaliteit-van-laboratoria

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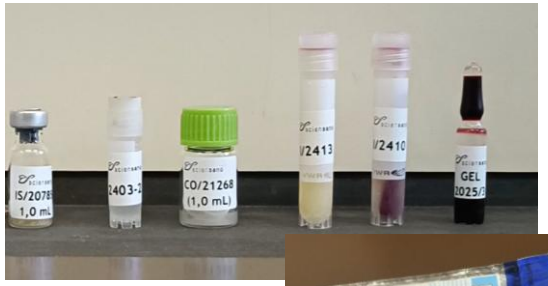
What do we do as EQA provider ?

Preparation of answer FORM



Preparation and packaging of samples

Preparation of shipment

Statistics & Reporting

-Support

-Providing extra/new samples (non arrival, technical problem)

-Counseling and Non-Conformities follow-up

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Which domains are we covering ?

Cardiac markers

Therapeutic drug monitoring

Molecular biology :
- Microbiology
- Genetic testing
- NGS

Andrology

Bacteriology

Drugs of abuse

Heavy metals

Infectious serology

Chemistry Electrophoresis

Rare diseases

Parasitology

Sciensano
Quality of laboratories

Anatomical pathology

Veterinary Medicine

Auto-immune diseases

HbA1c

POCT:
- Glucose
- Blood gasses
- Co-oxymetry

Allergy

Bone marrow

Lymphocyte subset counting/CD34

Alcohol

Immunohematology

Coagulation

Hematology

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Three EQA scopes; one goal : a better patient's care

Molecular Microbiology

Bacteria
Viruses
Parasites

Molecular biology (NGS)

Solid tumors
Hematological malignancies

Molecular biology (PCR/ISH/NGS)

Solid tumors
Hematological malignancies
Prenatal testing
Hematology & Bloodgroup

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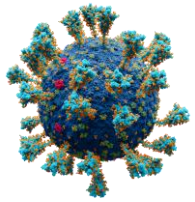

Molecular Microbiology EQA

Provided by Sciensano in collaboration with NRCs:

- Hepatitis viruses (HCV, HBV)
- STI (HPV; C. trachomatis; N. gonorrhoeae)
- T. gondii
- B. pertussis
- CMV in Newborns
- M. tuberculosis

Outsourced to another EQA provider (syndromic panels of QCMD):

- Respiratory pathogens (Influenza, RSV, Sars-Cov-2)
- Viruses in transplant (CMV, EBV, Adenovirus, BK virus, …)
- Viral meningitis (Enterovirus, HSV1, HSV2, VZV)

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https://www.sciensano.be/fr/qualite-des-laboratoires/eeq-biologie-moleculaire-microbiologie
https://www.sciensano.be/nl/kwaliteit-van-laboratoria/eke-moleculaire-biologie-microbiologie

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Assessing quality in EQA for MicroMolBio:

Presence or absence of variants

- **Based on:** -Confirmation by expert laboratories
  -Sample manifest

Genes/variants linked to nomenclature with regards to the clinical relevance (hot-spot variant)

Presence or absence of germs

- **Based on:** -Confirmation by expert laboratories
  -Sample manifest

Number of germs/volume

Clinical classifications

- **Based on:** -Belgian and international guidelines

Labs' method

Method Overview

Not assessed

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Three EQA scopes; one goal : a better patient's care

Molecular **Micro**biology

Bacteria
Viruses
Parasites

Molecular biology (NGS)

Solid tumors
Hematological malignancies

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https://www.sciensano.be/fr/qualite-des-laboratoires/eeq-ngs
https://www.sciensano.be/nl/kwaliteit-van-laboratoria/eke-ngs

Molecular biology (PCR/ISH/NGS)

Solid tumors
Hematological malignancies
Prenatal testing
Hematology & Blood groups

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https://www.sciensano.be/fr/qualite-des-laboratoires/eeq-biologie-moleculaire-examens-genetiques
https://www.sciensano.be/nl/kwaliteit-van-laboratoria/eke-moleculaire-biologie-genetische-onderzoeken

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Before 2015

Genetic tests reimbursed by RIZIV/INAMI nomenclature art. 33bis/33ter


HHS Public Access
Author manuscript
Nature. Author manuscript; available in PMC 2013 March 27.
Published in final edited form as:
Nature. 2012 September 27; 489(7417): 519–525. doi:10.1038/nature11404.
2013
Comprehensive genomic characterization of squamous cell lung cancers
The Cancer Genome Atlas Research Network

Reimbursement

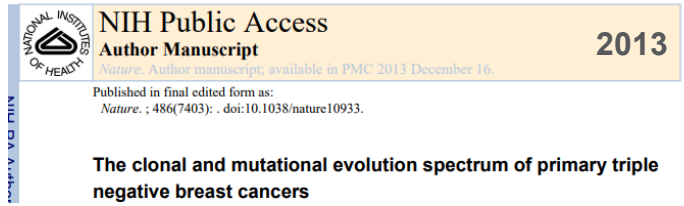
- Gene/variant dependent
- Technology independent


ANNUAL REVIEWS
Publications A-Z
Journal Information
ANNUAL REVIEW OF GENOMICS AND HUMAN GENETICS
Review Article
Unraveling the Genetics of Cancer: Genome Sequencing and Beyond
2011
NIH Public Access
Author Manuscript
Cell. Author manuscript; available in PMC 2013 July 20.
Published in final edited form as:
Cell. 2012 July 20; 150(2): 264–278. doi:10.1016/j.cell.2012.06.023.
2012
The origin and evolution of mutations in Acute Myeloid Leukemia

- From the 2010s, NGS became a key technology for cancer diagnostics
- NGS tests ↗↗↗

➔ Current nomenclature no longer suitable

➔ Large variation in implementation of NGS between labs


NIH Public Access
Author Manuscript
Nature. Author manuscript; available in PMC 2013 December 16.
2013
Published in final edited form as:
Nature. ; 486(7403): . doi:10.1038/nature10933.
The clonal and mutational evolution spectrum of primary triple negative breast cancers

No Standardization!

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Before 2015

2015

Health Service Evaluation (HSE) study

Centre du cancer Kankercentrum

isp wiv

WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE

KCE

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

KCE REPORT 240

NEXT GENERATION SEQUENCING GENE PANELS FOR TARGETED THERAPY IN ONCOLOGY AND HAEMATO-ONCOLOGY

Van den Bulcke M, *et al.* . Next generation sequencing gene panels for targeted therapy in oncology and haemato-oncology. Health Technology Assessment (HTA) Brussels: Belgian Health Care Knowledge Centre (KCE).
2015. KCE Reports 240. D/2015/10.273/26

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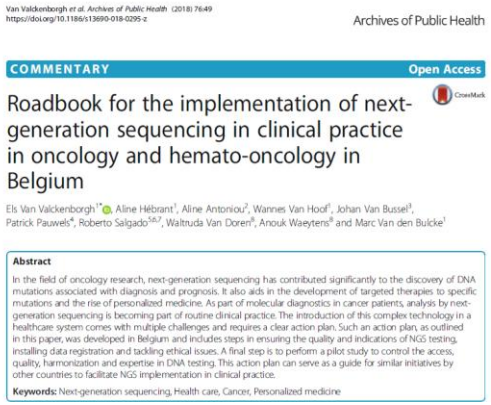
Before 2015 → 2015 → 2016 - 2020

Belgian NGS Roadbook

❑ 3 years of Pilot Study

➔ Guide for implementation of Next-Generation-Sequencing (NGS) in Routine Diagnostics in (Hemato)-Oncology in Belgium



Van Valckenborgh et al. Archives of Public Health (2018) 76:49
https://doi.org/10.1186/s13690-018-0295-z

Archives of Public Health

COMMENTARY Open Access

Roadbook for the implementation of next-generation sequencing in clinical practice in oncology and hemato-oncology in Belgium

Els Van Valckenborgh[1*], Aline Hébrant[1], Aline Antoniou[2], Wannes Van Hoof[1], Johan Van Bussel[3], Patrick Pauwels[4], Roberto Salgado[5,6,7], Waltruda Van Doren[8], Anouk Waeytens[8] and Marc Van den Bulcke[1]

Abstract

In the field of oncology research, next-generation sequencing has contributed significantly to the discovery of DNA mutations associated with diagnosis and prognosis. It also aids in the development of targeted therapies to specific mutations and the rise of personalized medicine. As part of molecular diagnostics in cancer patients, analysis by next-generation sequencing is becoming part of routine clinical practice. The introduction of this complex technology in a healthcare system comes with multiple challenges and requires a clear action plan. Such an action plan, as outlined in this paper, was developed in Belgium and includes steps in ensuring the quality and indications of NGS testing, installing data registration and tackling ethical issues. A final step is to perform a pilot study to control the access, quality, harmonization and expertise in DNA testing. This action plan can serve as a guide for similar initiatives by other countries to facilitate NGS implementation in clinical practice.

Keywords: Next-generation sequencing, Health care, Cancer, Personalized medicine

KEY COMPONENTS

- ➢ Creation of a national commission for personalized Medicine (ComPerMed)
- ➢ Development of NGS Guidelines and dedicated external quality assessment
- ➢ Adaptation of reimbursement system

Standardization

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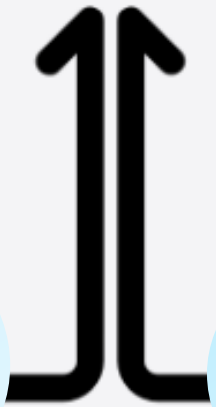
Before 2015 → 2015 → 2016 - 2020 → 2025 → Current situation

National Institute for Health and Disability Insurance (RIZIV/INAMI)



Nomenclature

➔Gene/variant dependent
➔Technology independent

NGS Convention

➔Exclusively for NGS tests In context of (Hemato)-Oncology

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Assessment of quality in standard NGS EQA in MolBio:

Presence or absence of variants

- **Based on:** -NGS data of the sample manifest
  -Labs' consensus
  -Experts' advises

Genes/variants linked to nomenclature with regards to the clinical relevance (hot-spot variant)

Only Regions included in the NGS convention

Therapeutic Conclusion

Not assessed

Biological & clinical classifications

- **Based on:** -Labs' consensus
  -Belgian guidelines BELAC 2-405-NGS R4-2023
  -Experts' advises

VAF

Not assessed

Labs' method

Method Overview

Not assessed

Coverage of regions required by the NGS convention

FASTQ and BAM files analysis

Feedback given without assessment

Assessing quality of NIPT EQA:

Assessment of clinical protocol

- **Based on:** -ISO15189
  -BeSHG guidelines
  -International recommendations

mock case based on the analysis request of each lab

Genotyping and Interpretation

- **Based on:** -Sample manifest

Interpretation (High/Low risk), invasive test obligation, test limits, fetal sex if required

Clerical accuracy

- **Based on:** -Belgian and international guidelines

Patient ID (Name, DOB), sampling date, date of report, gestational age

Labs' method

Method Overview

Not assessed

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Follow-up

Determination of True value and validation by committee of experts :

- ❑ False-negative rate
- ❑ False-positive rate
- ❑ Classification errors with impact for patient

Verification of non-conformity, action plan and deadlines by Sciensano

- technical problem
- human error
- region(s) not covered

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Challenges

- Difficulty in assessing completely the scope
- Difficulty in finding good EQA samples
- Disparity between scopes: specific needs

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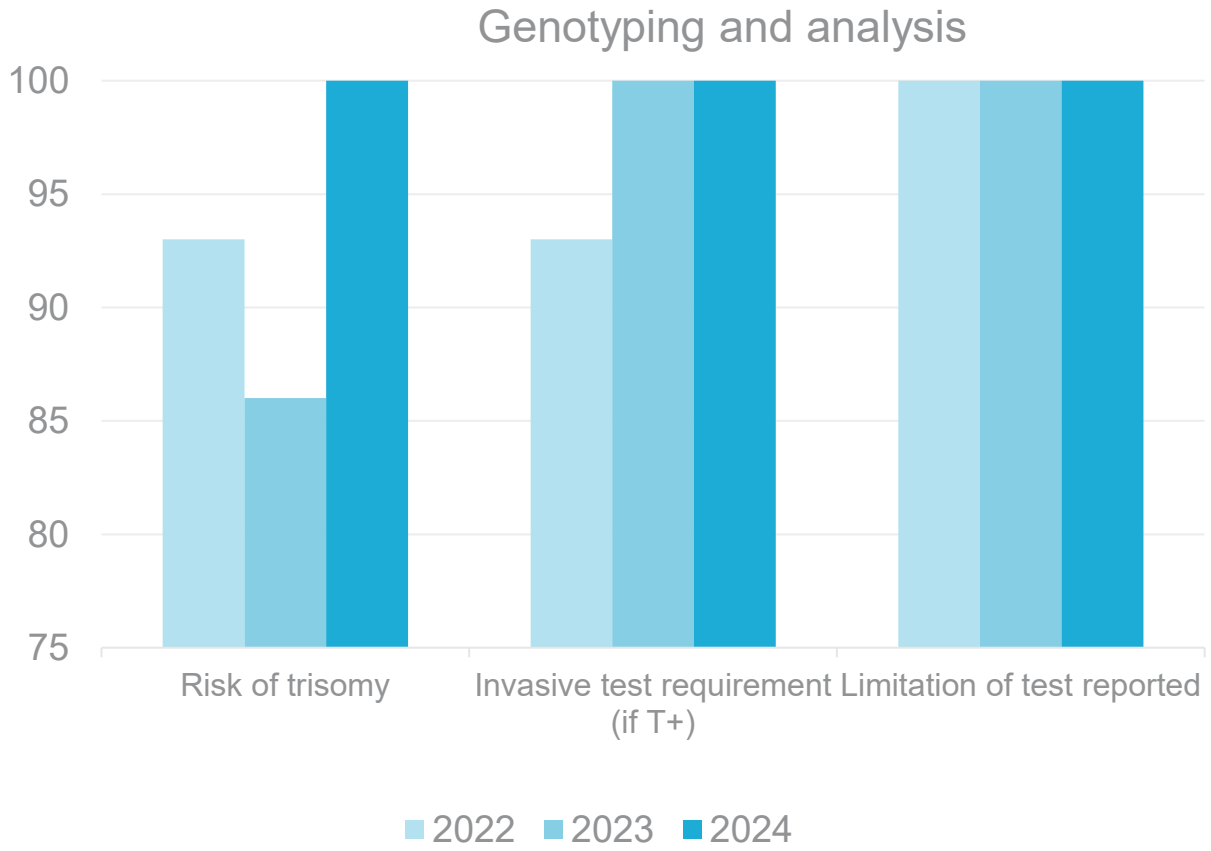
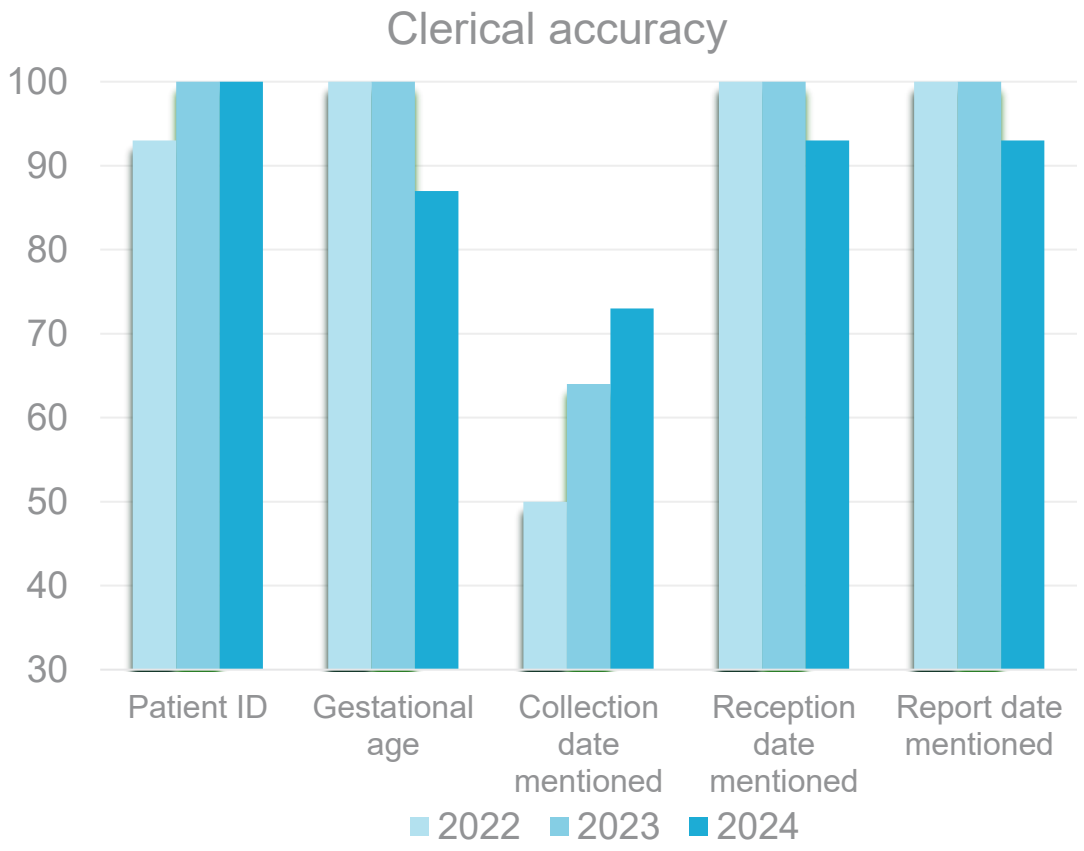
Example:
Laboratories performances to NIPT EQA





- Specifically adapted to the Belgian EQA programs of Sciensano
- Improvements in standardization: reporting, classification and annotation
- Belac accreditation for EQA provider - ISO17043
- Samples closer to clinical reality
- Development and validation of EQA for other technologies :
  - Challenging expert input
  - HRD, OGM, whole genome,…

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Committees of experts
&
QL Team

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