Gen-Bio
Biologie Médicale

Mandatory accreditation of medical laboratories in France:

how to best reconcile regulatory and normative requirements for cytogenetics ?

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Background
The reform of the medical biology in France

- **Article 69 of the Hospitals, Patients, Health, Territories (HPST) Act (Law n° 2009-879 of 21 July 2009)**

"provide better guarantees on the quality of medical biology examinations" by setting up a procedure for the accreditation of medical laboratories

- **Ordinance n°2010-49 of 13 January 2010 ratified by Law n° 2013-442 of 30 May 2013**

*« **Art. L. 6221-1.** – A medical laboratory, private and public, can not perform medical biology examination without accreditation. »*

Background
The reform of the medical biology in France

Accreditation of Medical Laboratories
= Regulatory area

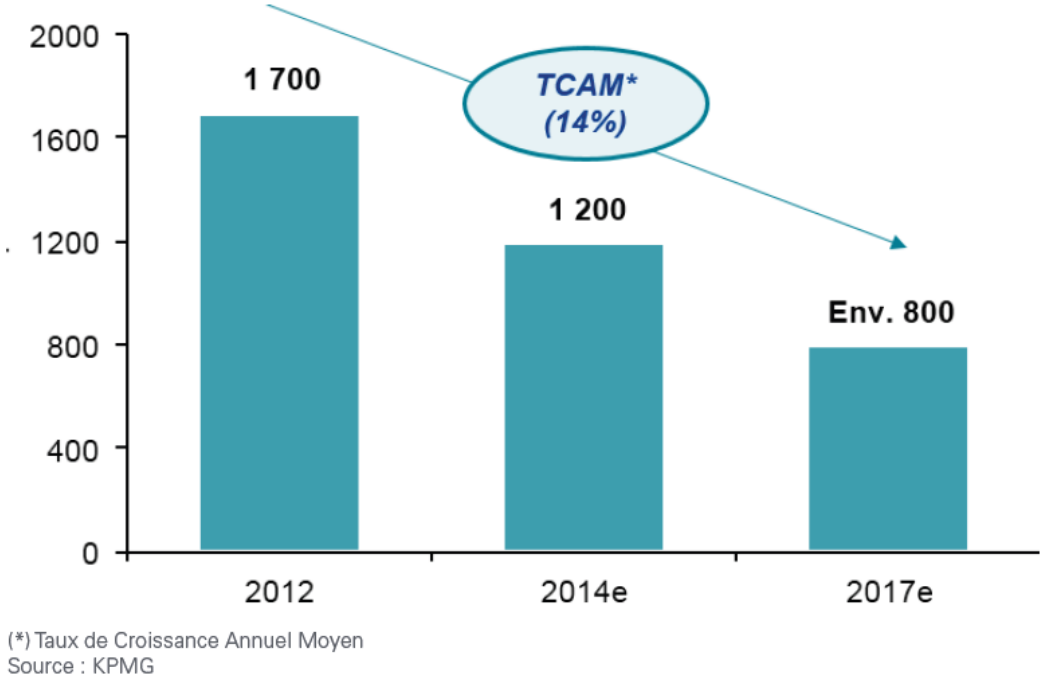
Attestation constitutes a formal demonstration of the competence of a medical laboratory to carry out specific conformity assessment tasks in agreement with the standards

Schedule for medical laboratories accreditation

DATE	REGULATORY REQUIREMENTS
01/11/2013	No laboratory could work after that date without having proved its effective entry into the accreditation process ⇨ **1384 laboratories have demonstrated their effective entry in the process**
31/10/2016	All medical laboratories, private or public, must be accredited for 50 % of their activities with at least ***one examination*** accredited per family ⇨**by April 30th 2015, all medical laboratories performing medical examinations had to submit an accreditation request :** > 900 requests received (application & extension of scope)
31/10/2018	All medical laboratories, private or public, must be accredited for 70 % of their activities
31/10/2020	All medical laboratories, private and public, must be accredited for the totality of their activities.

Organisation of medical laboratories

Number of technical platform – Laboratories with technical equipment 2012 – 2017 (estimation)



(*) Taux de Croissance Annuel Moyen
Source : KPMG

https://www.kpmg.com/FR/fr/IssuesAndInsights/ArticlesPublications/Documents/Laboratoires-analyses-medicales-fran%C3%A7ais.pdf

The French Committee for accreditation COFRAC

- Unique national accreditation body recognized by law

- In compliance with the European Regulation n° 765/2008 :
  - accreditation is a public authority activity
  - the national accreditation body operates on a non-profit basis
  - all interested parties are involved in the work of the national accreditation body
  - the national accreditation body fulfils the requirements of ISO/IEC 17011, particularly in terms of independence , impartiality, transparency, competence of its personnel

- Passed with success the peer evaluation organized by the EA and is signatory to the EA-MLA

European co-operation for Accreditation

The French Committee for accreditation COFRAC

4 sections manage the accreditations:

- Laboratories
- Inspection
- Certification
- Healthcare

❖ **in charge of the accreditation of medical laboratories** (SH REF 00) according to NF EN ISO 15189 (+ 22870 : POCT)

❖ **a permanent team of 34 people including 3 medical biologists,**

❖ **90 lead assessors and 217 technical assessors**

The HEALTHCARE SECTION : Activity

	12/2009	12/2012	12/2013	12/2014	05/2015
Accredited organism	**156**	**206**	**272**	**485**	**559***
Number of sites	156	510	975	1718	1997
including hospitals	**-**	**13**	**29**	**129**	**160**

* : 32 structures are not medical laboratories

In cytogenetics (somatic and constitutional genetics – 05/2015)

- **15** medical laboratories accredited in cytogenetics (11 in constitutional genetics)
- **7** technical assessors specialized in cytogenetics

In France : > 70 structures performing cytogenetics examinations
(DPN, Genetics activities)

Recruitment of new technical assessors is necessary

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Technical assessment

The technical assessment of medical laboratories is performed by medical biologists (either physicians or pharmacists or a person who meets the conditions for the exercise of medical biology)

Training : 4 days of theoretical and practical courses
and a first assessment as a trainee

Technical assessors perform 5-6 missions per year, **but** this may be less on highly specialized areas for which there are few applications for accreditation.

The assessment : Standards

… conducted by a lead assessor and a technical assessor

- **NF EN ISO 15189** (no obligation of means)

- **SH REF 02 « SPECIFIC REQUIREMENTS FOR THE ACCREDITATION OF LABORATORIES OF MEDICAL BIOLOGY »**

  - ❖ the legislative and regulatory provisions that apply for accreditation

  - ❖ the standard requirements and the rules covered by Cofrac, established in agreement with the positions adopted by EA and ILAC in accordance with standard NF EN ISO/IEC 17011

- **SH REF 08 « EXPRESSION AND ASSESSMENT OF ACCREDITATION SCOPES »**

- **…**

www.cofrac.fr

Characteristics of the cytogenetic accreditation

Discipline which is very regulated in France :

- An administrative approval is required from the laboratory, which is delivered by the Regional Health Agency (ARS), renewed every 5 years

- Biologists (physicians and pharmacists) are accredited by the French Biomedecine Agency (ABM) for 5 years

- Numerous specific regulations to carrying out biological examinations :
  - Written consent from the patient
  - Prescriber's consultation's certificate
  - Bio banking procedures
  - Particular procedures for the archives
  - Yearly requirement for an activity report for the ARS and the French ABM


Brainstorming
PDCA
Law nº 2013-442
SH-REF-02
SH-INF-50
SH-GTA-06
Standard
NF EN ISO 15189
7M
SH-FORM-44
Accreditation
5M
SH-GTA-04
ISHIKAWA
ISO 9001
FMECA

Characteristics of the cytogenetic accreditation

Problematics in setting up the accreditation in a cytogenetic laboratory

3 examples which can generate deviations:

- Qualification and authorization to practice for the cytogeneticists
- Biological examination by referral laboratories
- Validation of examination procedures

Ex 1 : Qualification and authorization to practice for the cytogeneticists

- Laboratories weak point
- Approval of the ABM is compulsory but not sufficient, however the assessors check their validity (SH-REF-02 page 9)
- The laboratory must define objective criteria's of qualification
- Having the necessary qualification does not automatically give clearance
    - ❖ Qualification = I'm able to
    - ❖ Authorization = I'm authorised
- Reassessment of the competences

Ex 2 : Genetic Examinations by the referral laboratories

- The Genetic laboratories are very specialised, but all of them do not carry out all the genetic examinations
- They are brought to refer rare biological examinations
- The genetic examinations done by referral laboratories often create deviations because the laboratories do not respect the requirements of the NF EN ISO 15189 standards nor SH-REF-02 (section 4.4/4.5)
- Contradiction with the 27th of May 2013 Decree ?

Ex 2 : Genetic Examinations by the referral laboratories

4.4 Service agreements

4.4.1 Establishment of service agreements

The laboratory shall have documented procedures for the establishment and review of agreements for providing medical laboratory services.

Each request accepted by the laboratory for examination(s) shall be considered an agreement.

Agreements to provide medical laboratory services shall take into account the request, the examination and the report. The agreement shall specify the information needed on the request to ensure appropriate examination and result interpretation.

4.4.2 Review of service agreements

Reviews of agreements to provide medical laboratory services shall include all aspects of the agreement. Records of these reviews shall include any changes to the agreement and any pertinent discussions.

When an agreement needs to be amended after laboratory services have commenced, the same agreement review process shall be repeated and any amendments shall be communicated to all affected parties.

Ex 2 : Genetic Examinations by the referral laboratories

4.5 Examination by referral laboratories

4.5.1 Selecting and evaluating referral laboratories and consultants

The laboratory shall have a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline.

4.5.2 Provision of examination results

Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) shall be responsible for ensuring that examination results of the referral laboratory are provided to the person making the request.

- Contradiction with the 27th of May 2013 Decree ?

Ex 2 : Genetic Examinations by the referral laboratories

SH REF 02

4.5- Analyses forwarded to referral laboratories

[...]
The LMB specifies the methods for this transmission in its QMS documentation:
-**Information to the patient and the requester of the transmission to another laboratory of one or more biological samples with the name of the referral laboratories**;
...
- **Except where there is a clear emergency, communication to the patient and the requester of the results with interpretation by the sub-contracting laboratory**. The results may be communicated either in two individual reports, either in a single report that distinguishes between the examinations validated and interpreted by the LMB and those by the sub-contracting laboratory. If necessary, all of the examination results are interpreted;
- **Conservation by the LMB of the results reports issued by the referral laboratory for a period identical to the period for conserving its own reports.**
These methods are specified by decree.
The LMB which transmits the biological samples is not discharged of its responsibilities to the patient (L.6211-19).
The operations in the pre-analytical and post-analytical phases carried out on the biological sample transmit to the referral laboratory are part of the LMB's activities and must be controlled under the standard.

Ex 2 : Genetic Examinations by the referral laboratories

SH R

Décrets, arrêtés, circulaires

May 2013 Decree

4.1. Modalités de communication du résultat au patient

Le résultat d'un examen génétique ne doit pas être directement communiqué au patient par le laboratoire de biologie médicale mais par le prescripteur. Il s'agit d'une dérogation à l'article L. 6211-2 du code de la santé publique.

The prescriber is the only person who can communicate the result to the patient

7.2. Le compte rendu

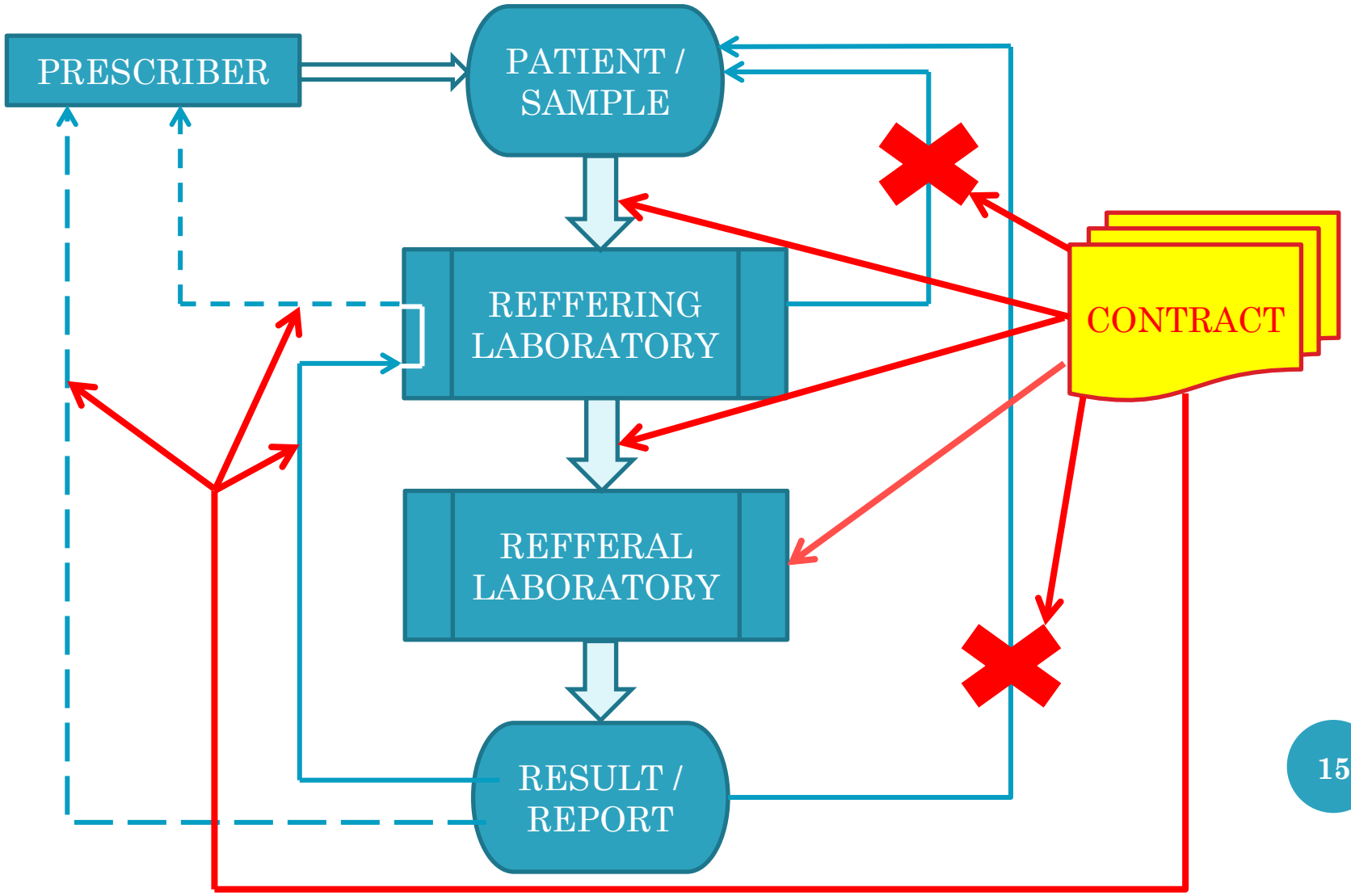
a) Préambule :

Le laboratoire qui réalise l'examen de génétique doit transmettre le résultat et le compte rendu au prescripteur.

Dans la situation où plusieurs laboratoires interviennent pour la réalisation des examens génétiques (travail en réseau), le laboratoire qui rédige le compte rendu et rend le résultat au prescripteur en transmet une copie aux autres laboratoires impliqués (laboratoire ayant reçu initialement le prélèvement ainsi que les laboratoires ayant participé au diagnostic). C'est le LBM qui a réalisé le prélèvement qui demeure responsable de l'examen et doit communiquer le compte rendu au prescripteur.

The referral laboratory must transmit a copy of the report to the referring laboratory

Ex 2 : Genetic Examinations by the referral laboratories



Ex 3 : Validation of examination procedures

- Cytogenetic methods = qualitative methods
- Scope B validation
- Diagnostic specificity and sensitivity of the method
- Importance of the Risk assessment which must be exhaustive
- Qualification of the employees

SH-GTA-04

Conclusion

No contradiction between the NF EN ISO 15189 standards and the French regulations which apply to cytogenetics.

Five Ws and a H

That should come after every new story

The End

Thank you for your attention

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