Fédération des Associations d'Evaluation Externe de la Qualité

"PROPOSAL FOR HARMONIZED METHOD CLASSIFICATION SYSTEM FOR EXTERNAL QUALITY ASSESSMENT SCHEMES"

- FAEEQ -

HTTPS://WWW.FAEEQ.FR/

METHOD CLASSIFICATION SYSTEM : DEFINITION

Different names for this concept : nomenclature (closed EQALM WG), encoding table (French law)…

What is the concept and purpose ? :

Most of the EQA organizers use lookup tables to ensure that all responses are in a correct and uniform format and thus **facilitate the processing and analysis of the data** provided for participants.

This tables most often concern IVD Medical Devices (method classification system) but they can also concern matrix, units….

Extended purposes :

- **Allow the comparison and aggregation of data from different EQA organizers** (interesting for different projects as HALMA) ⇨ Currently the exchange of data is made very difficult by the fact that the same IVDMD can have different names and references depending on the country of distribution
- inform healthcare personnel of the **comparability of two results obtained from different laboratories** (safe care)

THE FRENCH SITUATION

In 2012, five non-profit EQA organisers formed a Federation called **FAEEQ** “Federation of EQA Associations”. Currently six associations are members (sont Asqualab, ABP, Biologie Prospective, CTCB, GBMHM and ProBioQual) (HTTPS://WWW.FAEEQ.FR/). They cooperate to pool their experience, their know-how and their expertise in the field of External Quality Assessment and constitute a privileged interlocutor of the supervisory authorities (DGOS, HAS, ANSM, etc.) in the implementation and application of the Medical Biology Reform.

From 2012, the FAEEQ created a common encoding table of IVDMD

THE FRENCH SITUATION

- 2016

The common coding table was made compulsory by decree as part of the reform of medical biology. The French Health Product Agency (ANSM) is designated as responsible for its coordination. it asks the FAEEQ to manage this table (creation and update).

  - The coding no longer concerns only the IVDMDs but also the result in its entirety: analysis (e.g. glucose), matrix (e.g. blood), units (e.g. g/L), standard for traceability.
  - This extension of the coding should essentially facilitate data exchanges between the ANSM and the EQA organisers (IVDvigilance, annual report ….)

- 2023
  - Labs should have implemented LOINC encoding for harmonizing the results delivered to the medical doctors, but this code doesn't assure the comparability of results.
  - Given this observation, the competent authorities have decided that the FAEEQ encoding table will also be used for patients (in process)

FRENCH ENCODING TABLE : BASIS OF ENCODING

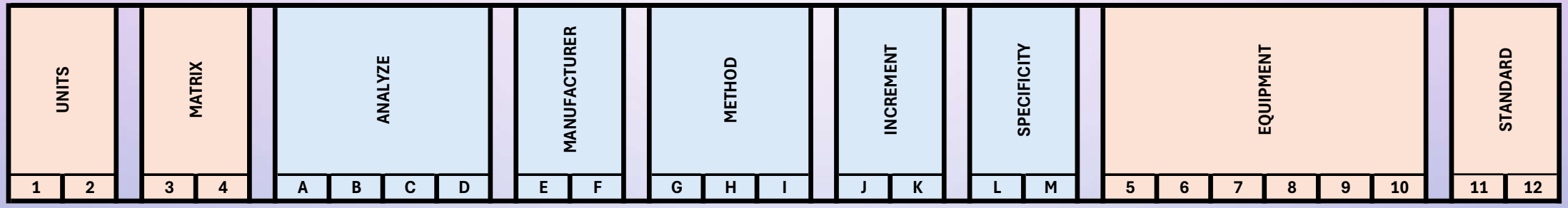
- These codes are a set of alphanumeric digits :The majority of digits are significant (alphanumeric characters or associations of characters corresponding to a method, a discipline* as hematolgy for exemple, a manufacturer…)
- One code corresponds to only one reagent (the same code cannot be used for two different disciplines or even two different analyses)
- On the other hand, the same reagent can have several codes if it allows different analyzes to be carried out (example autoimmunity: one reagent for ENA = as many codes as antigenic targets);
- An arbitrary number is attributed to the each IVDMD. If the same reagent has several codes, all its codes will have the same number in order to be able to link them. In the future, this code will be replaced by the device identifier UDI-DI (Unique Device Identification - EUDAMED).
  The UDI-DI will make it possible to overcome the problem of different names and references depending on the country. A harmonized method classification system for external quality assessment schemes could be possible on a European level.

** The disciplines are defined by the French Accreditation body (COFRAC)*

CODE STRUCTURE

RESULT : 25 digits

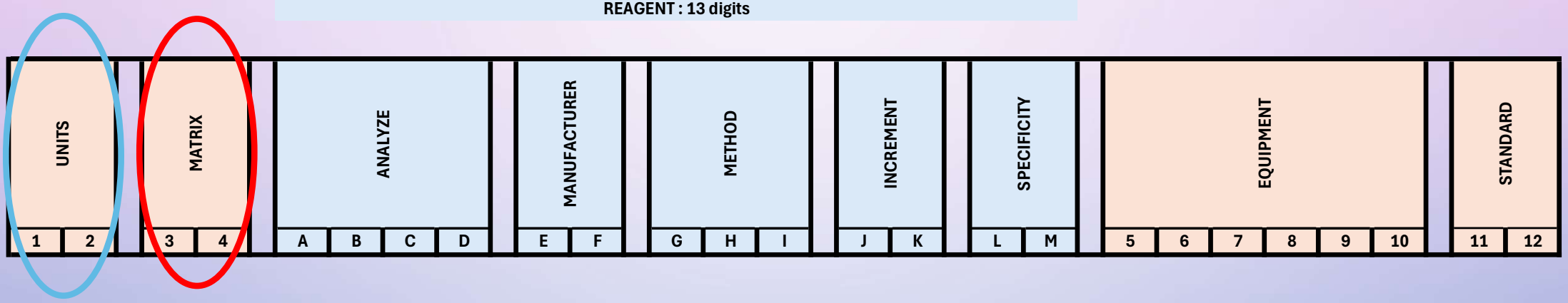
REAGENT : 13 digits



CODE STRUCTURE

RESULT : 25 digits

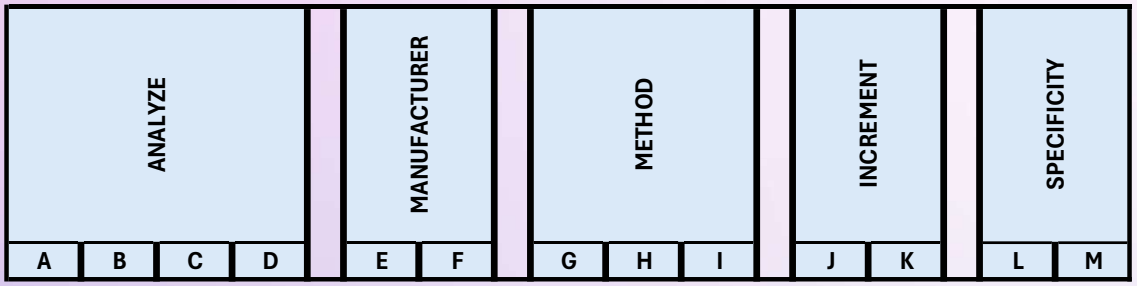
REAGENT : 13 digits



The units, in which the result is expressed, are coded on two digits: all equivalent units have the same code
Ex: g/L = mg/mL = a unique code

The Matrix has been removed from the reagent code (digits A to M) in order not to multiply the number of codes for a reagent because a same reagent can be used with different matrices (eg one reagent for glycosuria and blood glucose)

CODE STRUCTURE : METHOD (DIGITS G/H/I)



	Example	alphanumeric caracter attributed
• DIGIT G = General principle	Spectrophotometry/spectrometry	D
• DIGIT H = Detailed principle	Substrate assay with enzyme included in the reagent	E
• DIGIT I = Sub-principle	Enzyme/ UV Hexokinase	H

Method Code = DEH

BENEFITS OF ENCODING TABLES

= ensure comparability of results

That permits :

- For EQA organizers
  - possibility of creating peer groups
  - exchange of data between EQA Organisers,
- For Public Health : uniformity of data reporting to the clients of EQA organizations (competent authorities, accreditation Body, inspection, IVD vigilance…)
- For Doctors and Patients : right interpretation of results obtains in different labs
  - Table of method will be mandatory for the patient report (each lab with a same code will use the same name of the method in the reports). It will very soon be made available to medical laboratory software publishers;
- For WG GROUPS who needs aggregated EQA : harmonized data for their studies

DISAVANTAGES OF ENCODING TABLES

= **Time consuming = money consuming**

- all reagent instructions must be collected from manufacturers and when they refuse from users. They are to be analyzed in order to create the code of the reagent.
- The work is never finished (about 600 analyses coded at this time) and requires great responsiveness: new reagents, new methods, new analyses …

Thanks for your attention