

The unique expert system for combinatory biological and medical autoverification of patients' reports



- Easy to set up and customise
- Harmonises validation practices
- Improves patient safety and turnaround times
- Quality Control processes for accreditation (ISO 15189)
- Suitable for all configurations of laboratories and technical platforms

More than 25 years of autoverification

- More than 750 laboratories using our solution in France, Europe and Africa
 - More than 250 000 patients reports processed each day
 - More than 25 000 autoverification rules modeled





Expert system for medical autoverification



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VALAB[®]: the company

Located near Toulouse, France, the VALAB company is a spin-off of the EREMS company which originally developed the Valab expert system in the early years.

The VALAB company consists of a team of a dozen or so in-house staff and external consultants working to develop the Valab[®] expert system for computer-aided autoverification and biological validation, both for the French market and internationally.

Today, over 750 sites use Valab[®] daily in France, Europe and Africa to autoverify more than 250 000 patient reports each day.

The VALAB company is represented internationally by:

- Werfen in Benelux
- Dedalus in Italy
- Somadiag in Morocco and for all French-speaking African countries

The VALAB company is certified ISO 9001 for all of its activities.

Valab[®]: the validation expert

Valab[®] is the only computer-aided validation software able to take into account all of the data of a patient's report in order to perform biological validation *(demographic, contextual, inter-parametric, medical and technical parameters)*.

Valab[®] can be used with most laboratory information systems on the market (*bi-directional connection and integration of the autoverification results*).

Valab[®] proposes:

- a choice of standard modules for routine tests (*Biochemistry, Haematology, Coagulation, Blood gases*)
- a panel of additional tests belonging to more specialised disciplines (e.g. markers, hormones, serology, medication, toxicology, urinalysis, blood groups, etc.)
- a modeling tool to create autoverification rule models

In the age of laboratory accreditation (ISO 15189) and the increasingly consultative role of the biological clinical scientist, the Valab[®] system guarantees, in conformity with the requirements of the ISO standard, the systematic autoverification of all the patients reports, bringing safety, productivity and harmonisation to the practice of biological validation.

Valab[®] : working with the LIS

The integration of Valab[®] into the IT architecture of the laboratory is entirely transparent for clinical scientists who continue to validate on their LIS terminal screens with full integration of the autoverification results for each test ("flags"), without modifying their normal way of working:



General presentation

Objective

To set up an intelligent system for the autoverification of patients reports capable of improving the safety, reproducibility, quality and speed of rendering of test results to the patient.

Used like a filter, the Valab[®] system picks out and highlights the non-validated reports for which the intervention of the clinical scientist brings real biological and/or medical added value before authorisation is given for release of the results.

Moreover, in the context of a multi-site medical laboratory, Valab[®] allows to harmonise and monitor the practice of biological validation by bringing together the different clinical scientists thanks to the means of control that have been implemented.

Integration overview



Means of control

Users have at their disposal reference documents allowing them to ensure the implementation of the necessary means of control within the context of ISO 15189 accreditation:

- Qualification and Validation of Valab® by the Medical Laboratory : means of control, qualification and continuous monitoring
- Valab[®] Manufacturer's Information for Medical Laboratory Accreditation: useful information for the accreditation of medical laboratories

The main principles are based on the following criteria:

- Customisation of the parameter settings for each medical test: units, reference values, validation limits for results with no previous result, critical values, reference change values (RCV), maximum and critical delta-checks, mandatory validation option, threshold tests, etc.
- Initial qualification before routine use in production
- Continuous monitoring: statistical indicators, use of control test reports and sampling of actual reports with archiving of records as proof of good practice
- Management and control of user access rights
- Integration into the laboratory's Quality Management System (QMS)

Consultancy and expertise

The VALAB company brings all its expertise to users by accompanying them in particular during the parameter settings customisation / initial qualification phase:

- analysis of the statistical indicators in relation to the autoverification of each test result
- suggestions for modifications to the parameter settings to the key contact clinical scientist in the laboratory
- assistance through a remote maintenance link

Principles

Knowledge base

Originally developed in collaboration with the teams of the Rangueil University Hospital in Toulouse, France (professors P. Valdiguié, J.X. Corberand and B. Boneu).

Assessed by the CNEH (French National Centre for Hospital Expertise).

Expert system software

A logical representation and inference engine developed from research work. The software tool allows to reproduce the logic, complexity and combinatory power of human reasoning, by assessing and weighting each parameter taken into account during autoverification.

Overview

For the clinical scientist, meeting the demands of medical laboratory accreditation and the medicalisation of the profession requires the setting up of a particularly efficient organisation.

Valab[®] provides a solution to ensure, under the responsibility of the clinical scientist and in conformity with the requirements of the ISO 15189 standard, a systematic review of all the patients results before they are released.

This approach also makes it possible to perform biological validation using uniform and consistent criteria in the context of technical platforms and multi-site medical laboratories.

Modules

Biochemistry (62 tests)

Blood gases (10 tests)

Haematology (25 tests)

Coagulation (25 tests)

Additional modules and tests: approximately 200 tests already available in the catalogue, including markers, hormones, serology, medication, toxicology, urinalysis, blood groups, . . .

Supported tests (by speciality)

Biochemistry	Albumin Alk. phosphatase Alpha1 AGP Alpha1 globulins Alpha2 globulins Amylase Anion gap APO A1 APO B Beta globulins Bicarbonates C3 C4 Calcium Chloride Cholesterol	CK CKMB CKMB mass Coef. of saturation Cond. bilirubin Creatinine CRP Delta Na-Cl Erythrocyte Mg Ferritin Fructosamine FT3 FT4 Gamma globulins GGT Glucose	Glycated Hb GOT GPT Haptoglobin HDL Cholesterol IgA IgM Ionized calcium Iron Lactate LDH LDL Cholesterol Lipase Myoglobin Osmolarity/lity	Phosphate Plasma Mg Potassium Pre-albumin Sodium Total bilirubin Total protein Transferrin Triglycerides Troponin TSH Uncond. bilirubin Urea Uric acid
Blood gases	Base excess Hb (gas) HCO3	PCO2 PH PO2	Saturation in O2 Std Bicarbonates Total CO2	Total O2
Haematology	Abnormal lympho. Basophils Eosinophils Erythroblasts Erythrocytes ESR (1 h.) Hemoglobin	Hyperbaso. M. C. Immat. Granul. Leucocytes Leukoblasts Lymphocytes MCH MCHC	MCV Metamyelocytes Monocytes Myelocytes Neutrophils PCV Plasma cells	Platelets Promyelocytes RC Morpho Reticulocytes
Coagulation	Anti Xa aPCR APTT ATIII BT CAC D dimers	Ethanol F II F IX F V F VII + X F VIII F XI	F XII Fibrinogen INR PL Protein C Protein S QT/PT	RT TCT TCT/PS Unfr. heparin
Additional tests (a selection)	Biochemistry Aldolase Ammoniac BNP Angiotensin Conversion Enzyme Cockroft-Gault equation IgE (Total) NT Pro BNP Procalcitonin Blood gases Carboxyhemoglobin Desoxyhemoglobin Desoxyhemoglobin Methemoglobin Methemoglobin Haematology PDW RDW PCT MPV Hormones Beta HCG Beta HCG Beta HCG Free Calcitonin Corticotrophin (ACTH) Cortisol HCG Thyroglobulin	Markers 5' Nucleotidase 5-HIAA CAE AFP Beta 2 Microglobulin CA 125 CA 15-3 CA 19-9 CA 50 CA 72 4 Cyfra 21 Rheumatoid Factor Homocystein NSE PSA PSA Free SCC Thyroglobulin Antibody Thyroid Peroxidase (TPO) TPA TSH Binding Inhib. Antibodies Vitamin B12 Vitamin B9 Vitamin D	Medication Barbiturate Carbamazepin (Tegretol) Ciclosporine Digoxin Lithium Paracetamol Valproate (Depakine) Blood groups ABO Genotype ABO Phenotype Duffy Phenotype Kell Phenotype Kell Phenotype Kell Phenotype Kidd Phenotype (DCCEE) RH Phenotype (DCE) RH Phenotype (DCE) RH Phenotype (DCCEE) Rhesus (D-dd) Serology CMV IgG CMV IgG EBV IgA EBV IgA EBV IgM HAV Total Antibodies HBV DNA HCV Antibody HCV RNA	Helicobacter Pylori Antibodies HIV1 Antibody HIV1 p24 Antigen HIV1 Viral Load HIV1 Viral Load HIV1 Western Blot HIV1+2 Antibody Measles IgG Measles IgM Mycoplasma Pneum. Antibody Mycoplasma Pneumoniae IgM Paramyxovirus Antibody Paramyxovirus B19 Parvovirus B19 IgG Parvovirus B19 IgG Parvovirus B19 IgG Rubella IgM Salmonella - Widal Antibody Streptokinase Antibody Streptolysine Antibody Syphilis Antibody Syphilis TPHA Syphilis VDRL Toxoplasmosis IgG Toxoplasmosis IgM Whooping-cough IgA

Complementary data (by category)

Origin of the request	Cancerology Cardiology Digestive system Geriatrics Infectious diseases Intensive care	Internal medicine Metabolic diseases Nephrology Neuropsychiatry Obst. gyneco. Pediatrics	Pneumology Rheumatology Severe burn Traumatology Urology
Clinical and Therapeutic Information (CTI)	After dialysis Before dialysis Chemotherapy Cirrhosis Congenital deficiency Diabetes DIC Difficulty at sampling External Body Circulation Hemodilution Hemorrage Hepatitis	HIV Hyperthyroïdism Hypothyroïdism Infarction Liver insufficiency LMWH Lymph. nodes enlarg. splen. Malaria Myeloma Non fasting Oxygen Pancreatitis	Pregnancy Pre-operative Renal failure Thalassemia Thrombolysis Thrombolysis + heparin Thrombolysis + LMWH Transplantation Unfractionated heparin VKA VKA + heparin VKA + LMWH
Complementary Information (CI)	Air in syringe Bare nuclei Blasts Clotted sample Cold agglutinins Diluted sample Giant platelets Hemolysed sample	Heterozygote thalassemia Hyperlip. Plasma /hb/mch/mcmc Hyperlipemic plasma Hypersegmented neutro. Hypochr. Heteroz. thalass. Icteric plasma Micr. vis. check. wish	Most hyperbaso. mono. Polycythemia Some degranulated neutro. Some hyperbaso. mono. Tube insufficiently filled Umbilical blood Venous blood
Red cell morphology	Acanthocytes Anisochromasia Anisocytosis Aniso-poikilocytosis Aniso-poikilo-hypochromasia Aniso-poikilo-macrocytosis Aniso-poikilo-microcytosis Aniso-poikilo-targets Dacryocytes	Dual population Elliptocytes Howell-Jolly bodies Hypochromasia Hypochrom-microcyt-targets Macrocytosis Microcytosis Parasites Poikilocytosis	Polychromasia Punctuate basophilia Rouleaux Schistocytes Sickle cells Spherocytes Target cells
Additional items (a selection)	Symbolic tests Not done Unknown Negative Uncertain Positive Very positive Immunized Not immunized Seroconversion Vaccine active Genotype group A/A Genotype group A/B Genotype group A/O Genotype group B/B Genotype group B/O Genotype group B/O Genotype group A Phenotype group A Phenotype group A Phenotype group B Phenotype group B Phenotype group B Phenotype group O Origine Dossier Haematology Radiotherapy Other/Anesthesiology Other/Dermatolgy/Venereology Other/ENT Other/Foot specialist Other/Foot specialist	Other/Medical genetics Other/Muclear medicine Other/Nuclear medicine Other/Ophthalmology Other/Ophthalmology Other/Pharmacist Other/Pharmacist Other/Physiotherapist Other/Radiography/Imaging Other/Speech therapist Other/Stomatology/Dental TCI Alcoholism Anaphylactic shock Androgens Anemia Anesthetics Aneurysm & angioma Angiotensin antagonist Anti-asthmatic agents Antibepressants Antibepressants Antiepileptic drugs Antifungal agents Antibiparkinson agents Antiparkinson agents Antispasticity drugs	Cardiovascular risk factors Chemotherapy Chronic obstructive pulmonary disease Coma Congestive heart failure Contraceptive implant Contrast agents Cordarone Coronary syndrome Cystic fibrosis Deficiency diseases Immunodeficiency Immunoscintigraphy Immunoscintigraphy Immunoscintigraphy Immunoscintigraphy Immunoscintigraphy Immunoscintigraphy Inflammatory joint disease Insulin Leukemia (ALL-AML-CLL- CML) Leukocytosis Leukopenia Lymphoma Malnutrition Medical shock Medico-legal sample Tobacco dependence Transplant rejection Tuberculosis Under the influence of alcohol

Autoverification principle (cognitive model)

The expert system approach

The construction of human reasoning and the ensuing behavior are the result of a set of conscious (knowledge) and unconscious (experience) elementary intellectual processes.

The development of an expert system consists in:

- revealing the set of elementary processes
- · building a model capable of exploiting these processes
- validating the generated autoverification

Principle

The "intelligent" model which Valab[®] is based upon takes into account all the processes involved in the interpretation of a result according to a strategy that is close to human reasoning. The acceptability of a result depends on a truly combinatorial approach and not just on a simple classification in a pathological model. This makes it difficult to provide an exhaustive description of the autoverification process, as the result in no way depends on the application of an exclusive rule but on the contrary takes into account all the applicable rules.

A simple example

Let us consider a patient for whom we have the clinical information "hepatitis" and who has a highly abnormal GOT level at 800 IU 37°. These two items of information are compatible and can be modeled by a simple rule. However, if the patient also has a normal GPT level at 20 IU 37°, it is clear that this additional information makes the overall result incoherent. Only a combinatory approach makes it possible to describe complex models in this way.

The different categories of information used for autoverification

- Demographic age, sex
- Contextual hospital department, emergency, hospitalised
- Medical therapeutic and clinical information (TCI)
- Technical complementary information (CI)
- Inter-parametric coherence of results taking into account both the correlation between different tests and variations over time of all the tests (inter-parametric kinetics)

Strategy

The autoverification strategy used to interpret the acceptability of each parameter involves a number of steps:

Situate

- the value observed according to the demographic data (age and sex): normal, low or high value. Hemoglobin at 16 grams does not have the same significance for a man, a woman, or a newborn baby.
- the current result with regard to a previous result if one exists: decrease-increase, improvement-deterioration.

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Trigger all the rules applicable to the situation previously analysed

- Without anteriority correlation rules (lower or higher trend)
- With anteriority anteriority rules (lower or higher trend)

Each set of rules comprises on the one hand positive rules which allow the validation of (normally) abnormal results and on the other hand negative rules which prevent the validation of (abnormally) normal results.

Establish a summary of the acceptability of the result

- Flag (V) Valid
- Flag (A) not valid for "Anteriority"
- Flag (P) not valid for "Panic value"
- Flag (C) not valid for "Correlation"
- Flag (D) not valid for "Domain"

Results

Meaning

(V): This normal or pathological result, with or without anteriority, is validated

The value observed is both compatible and coherent with the other information available in the report, and in addition it falls within the field of competence of the system.

(P): This result is not validated as its value is critical and reserved for the clinical scientist

This information, called a "Panic value" (for example, high potassium at 8 mmol/l) has priority over the notions of Correlation and Anteriority. Each laboratory can define and set the critical limit values corresponding to its activity.

(D): This result is not validated as it falls outside the area of competence of the system

This indication means that the result is not validated because the report contains at least one item of information (or a test result) whose mere presence is sufficient to prevent the validation of the report, it is therefore excluded from the decisional "Domain" of Valab.

This type of information is either part of the autoverification (for example TCI "malaria") or arises from the way in which the parameters of the system have been set up by the user for one or more items of specific complementary information: department of origin, clinical and therapeutic information, etc.

(A): This result is not valid for a reason connected with the Anteriority of the parametere

This notion integrates the definition of the RCV (analytical delta-check and intra-individual variation), and adds a dynamic dimension by the combination of rules.

These rules modulate and adapt the acceptability of the variation observed according to the demographic or contextual data, and above all according to the kinetics (direction of change, amplitude, value) of the other test results.

(C): This result is not valid for a reason connected with the Correlation of the parameter

Beyond the normal values weighted for age and sex, this concept gives a dynamic definition of the acceptability of the result observed according to the contextual data and the values for the other tests.

Other flags

In order to make the interpretation of results more precise, there are also subcategories of expertise flags (C>, C<, c>, c<, A>, A<, a>, a<, P>, P<, DM) and technical flags (eT, eS, eU, eX, DQ, N).

Intelligence of the system

The intelligence of the system for "Anteriority" consists in its capacity to validate a large variation (greater than the RCV) if this variation is consistent with the other available data, but to block a slight or nil variation (less than the RCV) if this is incompatible with the variations observed for the other tests.

The intelligence of the system for "Correlation" consists in its capacity to validate a pathological result if this result is consistent with the other data (normally abnormal), but to block a normal result if it is incompatible with other results (abnormally normal). It follows therefore that a Correlation error may arise from:

- either the existence of a negative correlation between several incompatible elements
- or the absence or mere insufficiency of correlations which would make it possible to justify the abnormal result. This latter case is the more frequent and corresponds, for example, to isolated hyperglycaemia when there is no notion of endocrinology in the origin of the report (possible diabetes) and no notion of a reanimation or IC unit (possible glucose infusion).

Furthermore, the greater the anomaly (i.e. the further the value departs from the reference interval), the more validation will require the presence in the report of elements of correlation which by their weight and number will justify the result. For example, extremely high serum potassium cannot be justified by the notion of nephrology alone, but if the serum creatinine, urea, and calcium results are also available . . .

Conclusion

These last two groups of results (A) and (C) represent the true autoverification power of Valab[®] in its ability to reproduce the clinical scientist's reasoning.

Considering that the initial configuration is just a starting point, users must then customise the parameter settings to adapt the relevance and efficency of the system to their own operational requirements and the specific nature and context of the site (recruitment population, technique used).

Users can modify for each test the various basic parameter settings (units, reference values, validation limits for results with no previous result, critical values, RCV, maximum and critical delta checks, mandatory validation, threshold test, ...), but above all they can fine-tune the "weight" of the rules by adjusting the "sensitivity" parameter setting.

Sensitivity can be modified (neutral value equal to 1) selectively and independently for the "Anteriority" and "Correlation" of each parameter, thus affecting the weight of specific rules, in order to make the system more permissive (value greater than 1) or more restrictive (value less than 1) with regard to the acceptability of a test (normal or abnormal).

When in operation, the system automatically generates a set of statistical indicators and associated alerts which clearly point out the tests which have parameter settings that may require adjustment. These dashboards provide the user with indicators to monitor and fine-tune the system.

Examples of autoverification rules

• Correlation rule for serum calcium

If serum calcium is low,

If there is a result for creatinine,

If the value of creatinine is above 150 / 300 / 500 $\mu mol/l,$

<u>Then</u>

increase the acceptability of low serum calcium to 0.1 / -0.2 / -0.4 mmol/l.

• Anteriority rule for serum calcium

If there is a decrease of serum calcium with low serum calcium,

If there is a result and a previous result for creatinine,

If the creatininemia is above 300 $\mu mol/l,$

If the value of creatininemia increases,

If this increase is above 100 $\mu mol/l,$

<u>Then</u>

increase the delta-check of calcium by 10%.

• Clinical and therapeutic rule for pO2

If there is a result of pO2 superior to 100 mmHg, If there is oxygenotherapy,

Then

it is possible to validate such a pO2 value.

Negative rule for serum calcium

If there is a decrease of serum calcium with low serum calcium,

If there is a result and a previous result for total proteins,

If the value of the total proteins increases,

If this increase is above 5 / 10 g/l,

Then

decrease the delta-check of serum calcium by 5 / 10 %.

• Correlation rule for hemoglobin

If there is a low hemoglobin value,

If the patient is in an intensive care unit,

<u>Then</u>

decrease the acceptability value of low hemoglobin by 30 g/l.

 Negative rule for Prothrombin / Quick Time (PT / QT)

If the PT / QT increases by more than 8 seconds, If there is a result for Activated Partial Thromboplastin Time (APPT),

If there is an increase of APPT of less than 3 seconds,

Then

it is not possible to validate such a value of PT / QT.

Example of reasoning strategy

If there is a high value for GOT (e.g. > 300 UI/I to 37 $^{\circ}$)

Look for information which could justify this value:

- infarction disorders: high or very high value for CKMB, CK, myoglobin; patient in intensive care unit, clinical information on infarction
- liver disorders: high value for GPT, high or very high value for conjugated bilirubin, high value for C reactive protein, patient in gastrointestinal ward, information on infectious disease or acute hepatitis
- other context: liver or pancreatic disorder
- chemotherapy context

Check that no negative rule is present which could prevent the acceptability of such a GOT value (e.g. very low GPT value).

Note

The advantage of VALAB in comparison with conventional algorithmic systems, lies in the cumulative processing of all rules (positively or negatively) to increase or decrease the acceptability of each test result according to all the elements related to it: sex, age, correlated parameters, previous result, prescriber, CI and TCI.

Complementary modules and additional tests

What are they for?

They allow users to complete the panel of tests supported by Valab[®] by simply and easily adding new tests or specialities to the standard modules from a catalogue of available tests: markers, hormones, serology, medication, toxicology, urinalysis, blood groups, ...

Moreover, an autoverification rule modeling tool, called Auto-Expert, is included and proposes powerful functionality to:

- modify existing autoverification rules, based on demographic, contextual and interparametric criteria
- model new tests, based on demographic, contextual and inter-parametric criteria
- use an intuitive graphical interface (sliders, liens, checkboxes, ...) to describe the autoverification rules without any programming
- take advantage of the same principles of combinatorial modeling between autoverification rules as for the modules that already exist in Valab[®] (same inference engine)
- exchange customised tests between users (*Import / Export* function) or download updates from the Valab[®] web site <u>www.valab.com</u>



Example of an autoverification rule model for an additional test



Report autoverification examples

Example 1 (Biochemistry)

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Creatinine :	*663	µmo1/1	*423	29/03/1992 00h	0	Print	Bicarbonates	
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Fotal bilirubin :	3	µmol/l	2.1	29/03/1992 00h	0	Add		
2PT •	22	TH 37°	28	20/03/1002 005		Delete		
SOT ·	34	TH 37°	31	29/03/1992 000	0			
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Report validated

The highly abnormal values of this report (Urea, Creatinine, Potassium, etc.) and overall kinetics are perfectly integrated into the progressive context of renal failure. The foreground window shows the data which influence the validation of potassium.

Example 2 (Haematology)

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Report validated

Profuse bleeding and dilution in the case of major surgery (heart surgery for example) or intensive care. The foreground window shows the data which influence the validation of sodium.

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