*Fill one form per medical biology test*

|  |
| --- |
| **Medical biology test:** Click here to enter text.**Validation/verification file** version n° **of the** dd/mm/yy**General domain:** Click here to enter text.**Technical domain:** Click here to enter text.**Nature of the sample:** Click here to enter text.**Method used:** Click here to enter text.**Analytical process**: Click here to enter text.**Flexibility:** [ ]  no  [ ]  yes, please specify why: creation, adaptation field…  |

| **Method description** |
| --- |
| Analyte/Measurand : *For one analyte and several matrices, it will be necessary to proceed to a method validation for each matrix (urine, blood, CSF,…)* | Identify the triptych analyte, matrix and unit.  |
| Measurement principle: | Click here to enter text. |
| Measurement method :*join the supplier's instructions* | Click here to enter text. |
| Primary sample type:  | Urine, blood, …  |
| Matrix to be analysed :  | Urine, total blood, serum, plasma, DNA, frozen/fixed tissue …  |
| Amount of sample required for analysis: | Click here to enter text. |
| Type of container, additives *(sample holder, tubes, …)*: | Indicate the type of container: tube/additive/presence or absence of a separator, transport bottle/medium, swab,…  |
| Pre-treatment of the sample: | Centrifugation, dilution, extraction, adsorption, elution, concentration …  |
| Format of the raw data *(O.D. ratio, numerical data from camera)*, and format of the result: | Click here to enter text. |
| Precise if the result is a number on a continuous scale of values (know whether it is qualitative or not) : | e.g. score, titration is qualitative  |
| Precise if there is one result per measurand *(if there is a combination of several numerical results for 1 analysis result = qualitative):* |  Click here to enter text. |
| Specify the type of result : | Click here to enter text. |
| Units: | Click here to enter text. |
| CE-IVD marking: | yes / no |
| Instrument(s)*:* | list of automatic analysers, intermediate equipment, computer equipment and measuring equipment, connected or not, etc. |
| References of the reagent(s) and consumable(s):  | Supplier reference, version of the instructions |
| Particular environment requirements | Click here to enter text. |
| Calibration material *(references : IQC, supplier control samples,...)*  /number of levels and values: | Click here to enter text.  |
| External quality control: | EQA, quality control program of the du BCQ, interlaboratory comparison |

| **Analysis of critical points: step by step process** |
| --- |
| **Critical points to control** | **Modalities of control**Please indicate the references of the laboratory’s QMS | **Residual risks observed after analysis of critical points**If yes, control through IQC, EQC, dysfunctions, non-conformities, trend analysis, indicators … |
| **Review of requests**IdentificationTraining and information of personnel | Procedure for indentitovigilance,… | Click here to enter text. |
| **Sampling modalities**Preparation of the patientInformation of patients and collectorsNature and volume of the sampleType of containersAdditivesTraining of collectorsLogistic management (shuttles, transport enclosures)InterferencesControl at reception | Sampling instructions, transport modalities, …Acceptance/refusal criteria,… | Click here to enter text. |
| **Pre-treatment of the sample**Centrifugation, dilution,… | Click here to enter text. | Click here to enter text. |
| **Workforce (staff empowerment)**Competence and maintaining staff competenceAssessment of staff competencies and training, training planAvailability of staff to ensure compliance with the procedure (e.g. subjective reading tests) | staff competency records,Traceability of workstation occupancy,… | Click here to enter text. |
| **Environmental requirements** (e.g.: Temperature, organisation of premises, lighting,…) Conditions for preservation of samples (t°, …), of reagents (t°, …), Metrology/monitoring of thermal chambersEnvironmental requirements for the equipment or operatorEnvironmental conditions (static and/or dynamic over time)Daylight reading | Instructions for conservationMetrological recordsRequirements / instructions of the supplierRecords of environmental conditions,… | Click here to enter text. |
| **Reference of the reagent** (supplier reference, version) | Click here to enter text. | Click here to enter text. |
| **Stability, compliance at reception ...…**Water qualityMeasurement of resistivity / sterilityConservation and conditions of useMetrology of thermal chambers (mapping and monitoring of temperatures)Stock managementAcceptance of reagents upon receipt | Traceability of verificationsSupplier documentsMetrological traceabilityStock management procedure (including acceptance upon each delivery),… | Click here to enter text. |
| **Reference materials, IQC, technical validation**Reconstitution of calibrators, controlsMetrology of pipetsRespect of the reconstitution procedure | Metrological traceability, instructions for reconstitution,… | Click here to enter text. |
| **Equipment, software**Metrological requirements4 (specify critical parameters)Specific computer requirements[[1]](#footnote-1) (decision algorithms, connection, settings …)Monitoring of driftPeriodicity of maintenancesControl of equipment (metrological monitoring, traceability, …)ContaminationRespect of the operating procedure of the supplierEmbedded computer applicationsSettings, calibration, archiving data, … | Records of maintenances, Metrological traceability, IQC/EQABibliography and/or records of the on-site testSetup procedures,… | Click here to enter text. |
| **Repeat testing**According to the operating procedure in manual decision, computerised, decision algorithms...… | Click here to enter text. | Click here to enter text. |
| **IT transfers**Connections | Records of test cases,… | Click here to enter text. |
| **Serum bank – adding tests** | Click here to enter text. | Click here to enter text. |
| **Advisory services** | Click here to enter text. | Click here to enter text. |
| **Release of results – management of the report** | Click here to enter text. | Click here to enter text. |
| **Revision of methods** | Click here to enter text. | Click here to enter text. |

| **Conclusion of the analysis of critical points** |
| --- |
| Please indicate whether the method is *stricto sensu* the one defined by the manufacturer, if some steps are adapted or if the method is entirely created by the laboratory.Thus, the verification / validation will be adapted accordingly. |
| Click here to enter text. |

**Assessment of the performance of the method**

| **REPEATABILY** |
| --- |
|[ ]  **Not applicable** | Please justify |
|[ ]  **Bibliographic review** | Please specify the selected data and indicate the bibliographic references |
|[ ]  **Experimental study** |
|  | **Expected performance criteria:** |
|  | Click here to enter text. |
|  | **Samples** | **Number of values (N)** | **Mean** | **Standard deviation** | **CV** | **Supplier’s CV** | **CV from publications, learned societies** | **Conclusion** |
|  | Type of matrix(plasma,serum, IQC,…). | Click here to enter text. | Levels tested | Click here to enter text. | % | % | % | Compliant / non-compliant |
| **Arguments of the conclusion:** |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples |

| **INTERMEDIATE PRECISION** |
| --- |
|[ ]  **Not applicable** | Please justify |
|[ ]  **Bibliographic review** | Please specify the selected data and indicate the bibliographic references |
|[ ]  **Experimental study** |
|  | **Expected performance criteria:** |
|  | Click here to enter text. |
|  | **Samples** | **Number of values (N)** | **Mean** | **Standard deviation** | **CV** | **Supplier’s CV** | **CV from publications, learned societies** | **Conclusion** |
|  | Type of matrix(plasma,serum, IQC,…). | Click here to enter text. | Levels tested | Click here to enter text. | % | % | % | Compliant / non-compliant |
| **Arguments of the conclusion:** |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples |

| **INTER-OPERATOR VARIABILITY** |
| --- |
|[ ]  **Not applicable** | Please justify |
|[ ]  **Experimental study** |
|  | **Expected performance criteria (if appropriate):** |
|  | Click here to enter text. |
|  | **Assessed operators** | **Number of values (N)** | **Results of variability** |
|  | Operator 1 | Click here to enter text. | Click here to enter text. |
|  | Operator 2 | Click here to enter text. |  |
|  | … |  |  |
| **Arguments of the conclusion:***If appropriate, please indicate the control modalities put in place (e.g. double reading,…)* |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples |

| **DIAGNOSTIC SENSITIVITY and SPECIFICITY** |
| --- |
|[ ]  **Not applicable** | Please justify |
|[ ]  **Bibliographic review**  | Please specify the selected data and indicate the bibliographic references |
|[ ]  **Experimental study** |
|  | **Expected performance criteria:** |
|  | Click here to enter text. |
|  |

|  |  |  |
| --- | --- | --- |
|  |  | True result (reference method/ true status) |
|  |  | Positive | Negative |
| Result of the test | Positive | True positives  | False positives  |
| Negative | False negatives  | True negatives  |

Decision thresholds used for the test and/or the reference method: Click here to enter text. |
|  | **Specificity** | **Sensitivity** | **Negative predictive value** | **Positive predictive value** |
|  | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Arguments of the conclusion:** |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples, the prevalence of the concerned disease,… |

| **approach of TRUENESS** (from externalised ICQ) |
| --- |
|[ ]  **Not applicable** | Please justify |
|[ ]  **Bibliographic review** | Please specify the selected data and indicate the bibliographic references |
|[ ]  **Experimental study** |
|  | **Expected performance criteria:** |
|  | Click here to enter text. |
|  | **Samples** | **Number of values (N)** | **Values of the lab** | **Target****(peer group)** | **Bias / peer group** | **General mean (all techniques)** | **Bias / general mean** | **Bias limit value** | **Conclusion** |
|  | IQC level 1 | Click here to enter text. | Click here to enter text. | Click here to enter text. | % | Click here to enter text. | % | % | Compliant / non-compliant |
|  | IQC level 2 2 | Click here to enter text. | Click here to enter text. | Click here to enter text. | % | Click here to enter text. | % | % | Compliant / non-compliant |
| **Arguments of the conclusion:** |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples |

| **approach of ACCURACY** (from EQA and inter-laboratory comparisons) |
| --- |
|[ ]  **Not applicable** | Please justify |
|[ ]  **Bibliographic review** | Please specify the selected data and indicate the bibliographic references |
|[ ]  **Experimental study** |
|  | **Expected performance criteria:** |
|  | Click here to enter text. |
|  | **Samples** | **Values of the lab** | **Target****(peer group)** | **Bias / peer group** | **General mean (all techniques)** | **Bias / general mean** | **Bias limit value** | **Conclusion** |
|  | Click here to enter text. | Click here to enter text. | Click here to enter text. | % | Click here to enter text. | % | % | Compliant / non-compliant |
| **Arguments of the conclusion:** |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples  |

| **MEASUREMENT UNCERTAINTIES** |
| --- |
|[ ]  **Not applicable** | Please justify |
|[ ]  **Calculation of measurement uncertainty** |
|  |  **Measurement uncertainty » procedure or any document providing details of the calculations:** |
|  | Click here to enter text. |
|  |  | **Calculated uncertainties** | **Performance requirements**(please indicate bibliographic references) |
|  | **Quantification of uncertainty****(level 1) :** | Level 1 in absolute terms ± U or Level 1 in absolute terms ± U%  | Fidelity, trueness and uncertainty requirements  |
|  | **Quantification of uncertainty****(level 2) :** | Level 2 in absolute terms ± U or Level 2 in absolute terms ± U%  | Fidelity, trueness and uncertainty requirements  |
|  | **Quantification of uncertainty****(level xxx) :** | Level xxx in absolute terms ± U or Level xxx in absolute terms ± U%  | Fidelity, trueness and uncertainty requirements  |
| **Arguments of the conclusion:***Please describe the impact on opinion, interpretation and advisory services**Interpretation (Exploitation of data with regard to clinical relevance)* |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples |

|  **REFERENCE INTERVAL and/or threshold values****according to demographic data** |
| --- |
|[ ]  **Not applicable** | Please justify |
|[ ]  **Bibliographic review** | Please specify the selected data and indicate the bibliographic referencesIndiquer les valeurs de référence si différentes en fonction de l’anticoagulant. Tenir compte du sexe, âge… |
|[ ]  **Experimental study** | Click here to enter text. |
| **Arguments of the conclusion:** |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples |

|  **DECISION THRESHOLD** |
| --- |
|[ ]  **Not applicable** | Please justify |
|[ ]  **Decision threshold** | Taking into account measurement uncertainties |

| **MEASURING RANGE** |
| --- |
| [ ]  **Not applicable** | Please justify |
|  | [ ]  **Bibliographic review** | [ ]  **Experimental study** |
| **Detection limit:** | Sources and values | Values |
| **Limit of quantification:** | Sources and values | Values |
| **Upper limit of the linearity range:** | Sources and values | Values |
| **Arguments of the conclusion:** |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples |

| **INTERFERENCES** |
| --- |
| [ ]  **Not applicable** | Please justify |
|  | [ ]  **Bibliographic review** | [ ]  **Experimental study** |
| **Haemolysis** | Indicate supplier data | Overload test |
| **Turbidity** | Indicate supplier data | Overload test |
| **Bilirubin, jaundice** | Indicate supplier data | Overload test |
| **Drugs** | Indicate supplier data | Overload test |
| **…** |  |  |
| **Arguments of the conclusion:***Please indicate sample control modalities If the automated analyser check interferences, please provide control data.* |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples |

| **CONTAMINATION**(Equipment qualification) |
| --- |
| [ ]  **Not applicable** | Please justify |
|  | [ ]  **Bibliographic review** | [ ]  **Experimental study** |
| **Inter sample for sensitive parameters (e.g. HBs Ag, βHCG):** | Indicate supplier data | Overload test |
| **Inter reagent if necessary (e.g.: LDH and ALT, cholesterol and phosphate, lipase and triglycerides):** | Indicate supplier data | Overload test |
| **Arguments of the conclusion:** |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples |

| **ROBUSTNESS OF THE METHODE and STABILITY OF THE REAGENTS** |
| --- |
| [ ]  **Not applicable** | Please justify |
|  | [ ]  **Bibliographic review** | [ ]  **Experimental study** |
| **Critical elements tested (t°, pH, position on a stand or device, …)** | Indicate supplier data | On-site test |
| **Stability of the samples, stability of reagents after opening, embedded, …** | Indicate supplier data | On-site test |
| **Arguments of the conclusion:** |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples |

| **COMPARISON OF METHODS***Caution: Redo as many tables as there are backup or parallel methods* |
| --- |
|[ ]  **Not applicable** | Please justify |
|[ ]  **Experimental study** |
|  | **Expected performance criteria:** |
|  | concordance, statistical test associated probability … |
|  | Bibliographic data (suppliers, publications,…):  | References of the method, bring out relevant elements  |
|  | Compared methods:* Previous method
* Another method used in the laboratory (back up)
* Mirror equipment or POCT (Point-of-care testing)
 | Indicate the references of the compared methods or automated analysers |
|  | Number of measurements:  | Click here to enter text. |
|  | Range for comparison adapted to the activity of the laboratory: | Indicate minimum and maximum values of the measurement rage |
|  | Method of exploitation of results: | Indicate the statistical tests used, e.g. least rectangle regression line, least squares regression line, Passing–Bablok … |
|  | Equation of the regression line: | y = ax + b |
|  | Difference and /or ratio plot: | Indicate the number of deviants after having verified and documented them |
| **Arguments of the conclusion:** |
| The laboratory indicates the provisions put in place (e.g.: transitional and documented use of a correction factor |

| **COMPUTER AND CALCULATION DATA** |
| --- |
|[ ]  **Not applicable** | Please justify |
|[ ]  **Applicable** |
|  | **Transfer automated analyser – middle ware (mono or bidirectional)** | Evidence file at the laboratory. Explain provisions here.  |
|  | **Transfer middle ware – LIS (mono or bidirectional)** | Evidence file at the laboratory. Explain provisions here. |
|  | **Decision algorithm or expert rules** | Evidence file at the laboratory. Explain provisions here. |
|  | **Calculations and rounding rules**  | Evidence file at the laboratory. Explain provisions here. |
|  | **Manual entries** | Evidence file at the laboratory. Explain provisions here. |
| **Arguments of the conclusion:** |
| Conclusions and comments, any justification regarding the parameter itself, the number of analyses samples |

| **COMMENTS, IF ANY** |
| --- |
| Click here to enter text. |

|  |
| --- |
| **Implementation** |
| Authorized operator(s) who performed the method verification/validation:  | Identity of the laboratory operator(s)  |
| Procedure for method validation and flexible scope management: | reference and version of the procedure used |
| Study period | Specify from: dd/mm/yy to dd/mm/yyIndicate whether any previous results were taken over |

|  |
| --- |
| **Decision on fitness for purpose:**Date: Name of the biologist Visa |

|  |
| --- |
| **Routine implementation:**Date: Name of the biologist Visa |

|  |
| --- |
| **Established elements of monitoring:**Parameter monitoring rules (IQC) : Click here to enter text.Exploitation of EQA: Click here to enter text.Monitoring of measurement uncertainty and / or risk analysis: Click here to enter text.Dysfunction components and trend analysis: Click here to enter text.….Date : Name of the biologist Visa |

|  |
| --- |
| **Evolution of the method**:Nature of the evolution: Click here to enter text.Specify what is being done: Click here to enter text.Validate the fitness:Date Name of the biologist Visa |

1. To be filled in if necessary [↑](#footnote-ref-1)