*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**  Identification  Training and information of personnel | Procedure for indentitovigilance,… | Click here to enter text. |
| **Sampling modalities**  Preparation of the patient  Information of patients and collectors  Nature and volume of the sample  Type of containers  Additives  Training of collectors  Logistic management (shuttles, transport enclosures)  Interferences  Control 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 competence  Assessment of staff competencies and training, training plan  Availability 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 chambers  Environmental requirements for the equipment or operator  Environmental conditions (static and/or dynamic over time)  Daylight reading | Instructions for conservation  Metrological records  Requirements / instructions of the supplier  Records 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 quality  Measurement of resistivity / sterility  Conservation and conditions of use  Metrology of thermal chambers (mapping and monitoring of temperatures)  Stock management  Acceptance of reagents upon receipt | Traceability of verifications  Supplier documents  Metrological traceability  Stock management procedure (including acceptance upon each delivery),… | Click here to enter text. |
| **Reference materials, IQC, technical validation**  Reconstitution of calibrators, controls  Metrology of pipets  Respect 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 drift  Periodicity of maintenances  Control of equipment (metrological monitoring, traceability, …)  Contamination  Respect of the operating procedure of the supplier  Embedded computer applications  Settings, calibration, archiving data, … | Records of maintenances,  Metrological traceability, IQC/EQA  Bibliography and/or records of the on-site test  Setup 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 references  Indiquer 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/yy  Indicate 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)